UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

MAGNOLIA MEDICAL TECHNOLOGIES, INC., Plaintiff, v. KURIN, INC., Defendant.	C.A. No. 19-00097-CFC **JURY TRIAL DEMANDED**

JOINT CLAIM CONSTRUCTION BRIEF

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I. PLAINTIFF'S INTRODUCTION

This case is about inventions that have fundamentally transformed the way blood is collected from patients for sepsis testing. The gold standard for drawing blood for decades was a phlebotomist inserting a needle into the patient's vein and taking all of the collected blood for laboratory analysis. The problem was that microbes on the skin surface, environmental contaminants, and the like were in many cases collected with the blood sample used for testing. This resulted in an unacceptable number of false positive results—*i.e.*, the test result falsely indicated that the patient had a blood infection when, in fact, they did not.

Beginning in the early 2000s, Dr. Richard Patton began exploring alternatives to the traditional approach. Magnolia's patents resulted from Dr. Patton's early work and his subsequent work with co-inventor Gregory Bullington. Magnolia's inventions have dramatically reduced false-positive blood tests for sepsis. By preventing false-positive results, harmful patient mistreatments and unnecessary use of antibiotics can be avoided, which helps stave off antibiotic resistance while saving the U.S. healthcare system billions of dollars of unnecessary healthcare costs annually.

There are 4 patents at issue in this case: U.S. Patent Nos. 9,855,001; 10,028,689; 10,039,483; and 10,220,139. The Court is being asked to construe six separate limitations that are found variously in the asserted claims.[1]

The differences between the parties' approaches to claim construction are stark. Per the guidance of *Phillips*, Magnolia asks the Court to give the common and well-understood words used in the claims their plain and ordinary meaning. Magnolia relies on bedrock principles of law and offers constructions that are both faithful to the patents and understandable to a fact finder

Kurin, in sharp contrast, takes a "throw-it-against-the-wall, and see-what-sticks" approach, in an effort to improperly narrow the claims.[2] It insists that four of the six terms should be construed as means-plus function, despite the fact that none of the four terms use the word "means," and all of the claims recite definitive and well-understood structure. Indeed, on three of the four terms, Kurin's expert did not offer an opinion supporting Kurin's means-plus-function proposal.

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[1] Kurin originally sought construction of ten terms. D.I. 48-1. Kurin subsequently agreed to Magnolia's construction for four of those ten terms. *See* Kurin Answering Br. at 30-31 ("blood sequestration device" and "bodily fluid sequestration device"), 31 ("valve disposed in the first lumen") and 31-32 ("flow control mechanism").

[2] Kurin's approach started early. Claim construction began on September 30, 2019 when the parties exchanged a list of terms for construction. D.I. 24 ¶ 15. Kurin proposed *29 terms* for construction. JA0001-11 (2019-09-30 Kurin Proposed Terms). In contrast, Magnolia proposed four terms, and the parties reached agreement on the construction of Magnolia's terms prior to briefing.

Kurin's approach can also be seen in the substantial concessions and changes to the proposed constructions Kurin made in its Answering Brief. Kurin folded outright on three of the nine terms ("blood sequestration device," "valve disposed in the first lumen," and "flow control mechanism"). On four of the remaining terms ("initial volume," "diverter," "housing," and "junction"), Kurin substantially conceded that its initial constructions were fatally flawed.

Kurin's Answering Brief also makes clear that Kurin's proposals are contrary to black letter canons of claim construction and ignore the perspective of a person of ordinary skill in the art.

II. DEFENDANT'S INTRODUCTION

Context is always helpful to understanding, and in this case it is essential. The four patents asserted by Magnolia are part of an incredibly complex and seemingly intentionally obtuse set of dozens of patents. These patents reflect an unfortunately common strategy in modern patent prosecution, as Magnolia has sought to expand the scope of its patent coverage far, far beyond the actual inventions it disclosed in its original patent applications.

Each of the patents asserted here is a continuation of an earlier application (the '001 and '689 patents are the *ninth and tenth continuations* respectively in their family), and each was filed after Kurin's device was launched. Having Kurin's product at hand, Magnolia has used repeated continuation practice to try to

incrementally expand the scope of its claims – or at least create ambiguity as to scope – ultimately creating the forty-four claims that it now asserts against Kurin. The result is a set of complex, overlapping prosecution histories, patents with extensive functional claiming while avoiding any "express" means-plus-function language, and overlapping claim language that is a sort of "word salad," swapping new claim terms for old, and using the same terms in different ways. All of this creates ambiguity and sows confusion, which Magnolia now seeks to exploit.

This case also suffers from the assertion of far too many related patent claims. Magnolia asserted 82 claims – later reduced to 44 – targeting a single Kurin device. The dozens of asserted claims use seemingly endless variations of similar and/or overlapping claim terms, and Magnolia attempts to read all of them on the same Kurin Lock product. An unnecessary multiplication of this dispute, this is an inefficient use of scarce judicial resources. At most, Magnolia's asserted patents each reflect a single invention with a few possible embodiments. That's how they *should have been* claimed, how they *should be* construed, and how this dispute *should be* resolved.

Facing dozens of interrelated claims that use different language to claim the same functionality and all allegedly read on a single accused device, Kurin has consistently and appropriately sought to narrow the parties' disputes through the claim construction process. Kurin has continued through the briefing process,

eliminating issues wherever possible and refining the remaining issues. The fundamental problem, however, remains that Magnolia has asserted far too many related, overlapping claims against a single Kurin device.

To make matters worse, Magnolia has claimed key elements functionally – even ascribing the same function to different features in different claims – while studiously avoiding the use of words such as "means" that would flag these as functional claims. This attempted sleight of hand allows Magnolia's lawyers to feign disbelief at the assertion that these are means-plus-function claims. Yet the claim language itself leaves no alternative. Whether it is called a diverter, a housing, or a junction, a claim that simply uses a word and sets functional requirements for it is a means-plus-function claim, properly limited to the disclosed structures for performing the claimed function.

III. PLAINTIFF'S BACKGROUND OF THE TECHNOLOGY

A. U.S. Patent Nos. 9,855,001 and 10,028,689

The '001 patent (D.I. 48-3) and the '689 patent (D.I. 48-4) share the same specification and were filed by Magnolia co-founder and prominent pathologist, Dr. Richard Patton. Both patents are titled "Systems and Methods for Parenterally Procuring Bodily-Fluid Samples With Reduced Contamination."[3]

[3] "Parenteral" means through a route other than the mouth or alimentary canal, *i.e.*, by vein.

Through his long medical practice, Dr. Patton hypothesized—and then confirmed through clinical testing—that "[c]ontamination of parenterally-obtained bodily fluids by microbes may result in spurious microbial test results," and that such "[f]alse positive results from microbial tests can cause a patient to be unnecessarily subjected to one or more anti-microbial therapies…which may cause anguish and inconvenience to the patient, as well as produce an unnecessary burden and expense to the health care system." '001 Patent, 1:63-2:5.[4] To tackle this problem, Dr. Patton invented various systems and methods to reduce contamination. Among his core inventive concepts were "divert[ing] the flow of bodily fluids from a patient" such that "an initial volume of withdrawn bodily fluid is placed in one or more pre-sample reservoirs and is not used for the incubation in culture media." *Id.*, 7:49-50, Abstract. These concepts permeate each of the embodiments described and claimed in the '001 and '689 patents.

For example, as shown in Figures 3A/3B, one way of diverting an initial blood volume is through use of a single blood flow path. *Id.*, 5:20-47. Initially the blood (and the majority of the skin contaminants) flow through the single flow path into a "pre-sample reservoir." *Id.*, 5:20-23, 5:29-41. The flow path consists of a "first needle" that is inserted into a fluid-containing portion of a body (such as a

[4] Because the specifications for the '001 and '689 patents are substantively identical, Magnolia primarily cites to the '001 patent.

vein), *id.*, 5:2-9, a "second needle" that can be inserted into the pre-sample reservoir, *id.*, 5:20-23, and "sterile tubing" connecting the two needles, *id.*, 5:29-32. Through this flow path the blood travels into the pre-sample vessel, as shown in Figure 3A (annotations and color added):

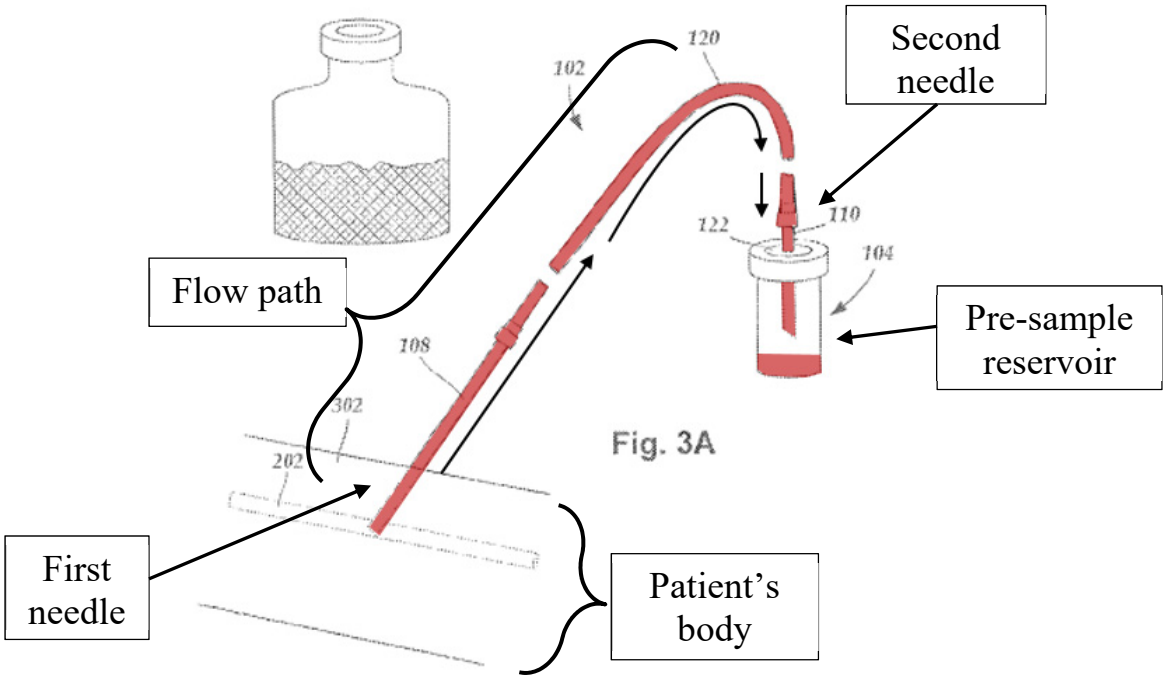


Fig. 3A

When the pre-sample reservoir fills, it can be removed and replaced with a "sample vessel" (*e.g.*, a container for collecting and testing blood). *Id.*, 6:16-18. A subsequent volume of blood from the patient travels through the same flow path but into the sample vessel, as shown in Figure 3B (annotations added):

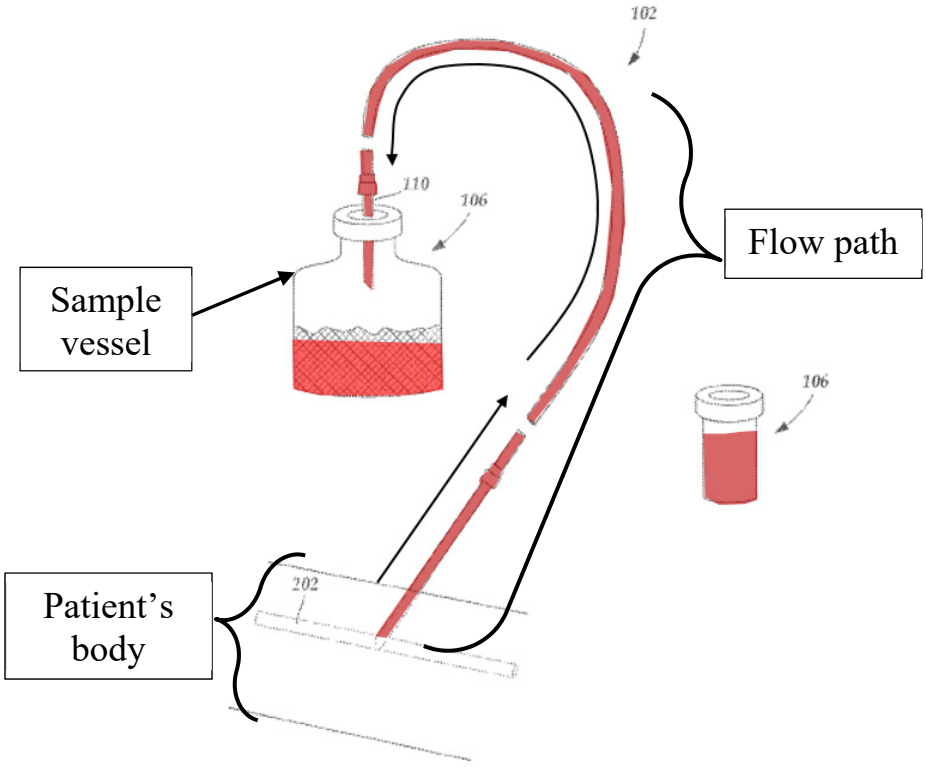
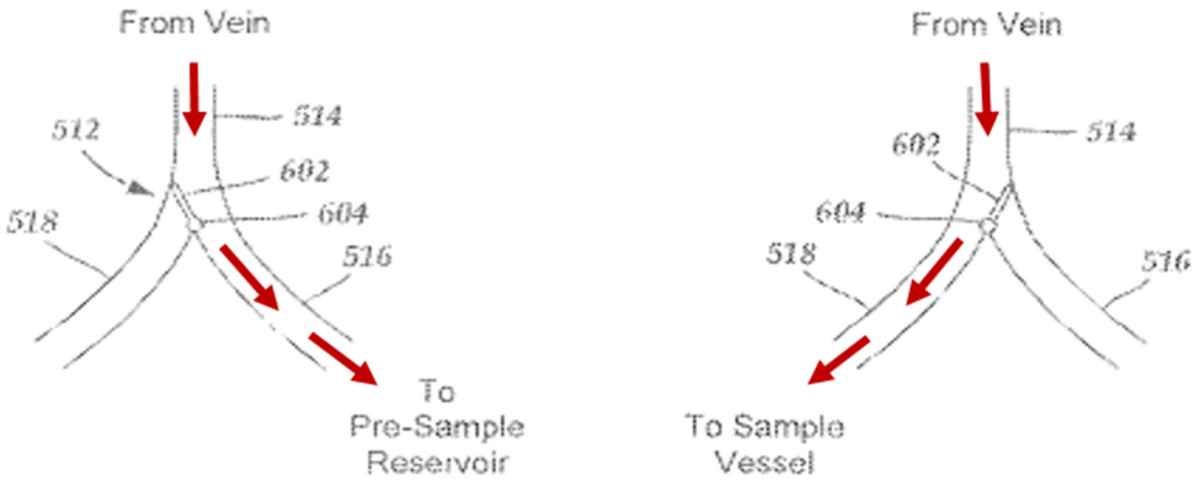


Fig. 3B

The pre-sample reservoir, with its potentially contaminated blood, is kept apart from the sample vessel, reducing the likelihood that testing the blood in the sample vessel will lead to false positives. *Id.*, 5:48-50, 5:56-62.

Another way of diverting an initial blood volume, as shown in Figures 6A/6B, utilizes a flow path from the patient that branches into two separate paths, one leading to the pre-sample reservoir and the other leading to the sample vessel:



Id., Figs. 6A, 6B (color added).

The patents explain that "[m]any different types of diversion mechanisms can be used to divert the flow of bodily fluids from a patient," *id.*, 7:49-50, and that the diversion can take place either "manually or automatically," *id.*, 8:23-26. In the example illustrated in Figures 6A/6B, the system includes a switchable valve (602) that pivots to allow blood to flow either toward the pre-sample reservoir or toward the sample vessel. *Id.*, 7:50-8:6.

B. U.S. Patent Nos. 10,039,483 and 10,220,139

Building upon the inventions of the '001 and '689 patents, Dr. Patton teamed up with his Magnolia co-founder, Gregory Bullington, and other engineers to design a robust platform of devices that could achieve the goal of widespread adoption of Dr. Patton's "Initial Specimen Diversion Technique," as it came to be known. *See, e.g.*, '483 Patent (D.I. 48-5), 7:13-16. Enacting practice changes within hospitals and converting practitioner behavior from the status quo (*i.e.*,

standard practice with no diversion) necessitated a blood collection system that would minimize the potential for external contamination, user error, and non-compliance.

In 2011 and 2012, this effort resulted in a broad array of design concepts and systems for achieving those objectives, which are reflected in the '483 patent and the '139 patent (D.I. 48-6).

IV. DEFENDANT'S BACKGROUND OF THE TECHNOLOGY

The medical community has long recognized that the initial volume of blood withdrawn after a needle is inserted into a patient's body contains a range of contaminants including bacteria and skin. Thus, for decades it has been standard practice to remove and discard the initial volume of blood before blood collection for uses like blood transfusions, where such contamination poses a risk to the receiving patient. Dr. Patton recognized that such contamination could be a source of false positive blood culture results, and in 2007-2008 he conducted clinical tests of his theory.

The results indicated that removing the initial volume of blood before collecting a blood culture materially reduces the number of false positive blood culture results. *See* Patton, *et al.*, *Innovation for Reducing Blood Culture Contamination: Initial Specimen Diversion Technique*, 48 J. Clinical Microbiology No. 12, pp. 4501–03 (Dec. 2010) (First Amended Compl., Ex. H (D.I. 5-8)). The

standard method of removing the initial volume of blood using a regular needle set, however, was cumbersome. The patents asserted in this case arise from Magnolia's attempts to develop a device to more easily perform what it calls Initial Specimen Diversion.

A. U.S. Patent Nos. 9,855,001 and 10,028,689

The '001 and '689 patents are continuations in the same patent family, and share the same specification. That specification first discloses the technique Dr. Patton used for his clinical research, a single line out of the patient without any "diversion mechanism." Magnolia's description of this "single blood flow path" technique (depicted in Figures 3A/B) is accurate.

The specification next discloses two embodiments of a concept that uses a single line coming out of the patient (514) into a "diversion mechanism" (512), and two lines out of the diversion mechanism (516, 518): (i) one to a reservoir that receives the initial flow of blood from the patient (504); and (ii) one to a sample collection bottle (506). The basic arrangement is shown in Figure 5 above. Two possible "diversion mechanisms" are disclosed. Figures 6A/B disclose a simple "switchable valve" 602 that can pivot to physically "seal" off one of the lines out

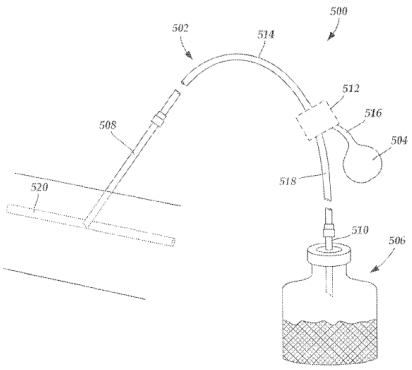


Fig. 5

of the diversion mechanism and divert flow into the other. [’001 patent, 7:49-8:27; ’689 patent, 7:50-8:28].

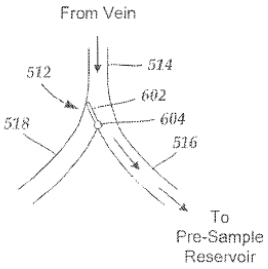


Fig. 6A

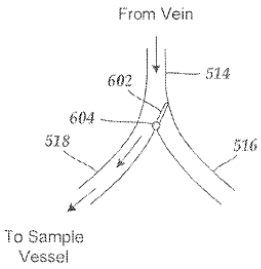


Fig. 6B

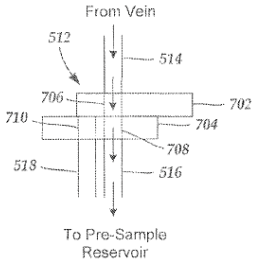


Fig. 7A

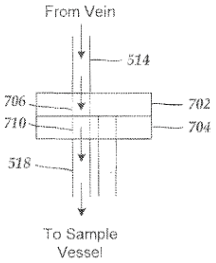


Fig. 7B

Figures 7A/B disclose a second diversion mechanism that uses “flow control blocks” that can slide relative to each other to physically close off one of the lines out of the diversion mechanism and divert flow into the other. [’001 patent, 8:28-9:15; ’689 patent, 8:29-9:15].

While the specification notes that “[m]any different types of diversion mechanisms can be used to divert the flow of bodily fluid from a patient,” [’001 patent, 7:49-50; ’689 patent, 7:50-51], these two are the only “diversion mechanisms” disclosed in the ’001/’689 specification. The specification does not include any other “catchall” language with respect to alternatives to these two “diversion mechanisms,” nor does it contemplate using anything other than a “diversion mechanism” to manage blood flow in such a device. No actual working device is disclosed; the specification is purely conceptual.

The original non-provisional application in the patent family that includes the '001 and '689 patents was filed over 12 years ago, on December 13, 2007. The applications for the '001 and '689 patents were filed March 13 and December 5, 2017. They are the ninth and tenth continuations in the family. None of the earlier patents in this family are asserted.

B. U.S. Patent No. 10,039,483

The '483 patent was filed on December 5, 2017, and is part of a different patent family than the '001 and '689 patents. It is the third continuation in its family, claiming priority to a non-provisional application filed on October 12, 2012, and it discloses an actual device designed to perform the initial specimen diversion process disclosed in the '001/'689 patents. This device is Magnolia's original Steripath product.

As described in the specification, the apparatus has six core components: (i) a housing; (ii) an inlet port; (iii) a "flow control mechanism"; (iv) a "first fluid reservoir;" (v) an outlet port that may connect to a "second fluid reservoir;" and (vi) an actuator to change to configuration of the flow control mechanism. ['483 patent, 8:33-9:34]. The first fluid reservoir receives the initial portion of the patient's blood, while the second fluid reservoir is a sample bottle. The "flow control mechanism" is the same functional component as the "diversion mechanism" in the '001/'689 specification, directing the blood flow from the inlet

port into the "first fluid reservoir" in a first configuration, then to the outlet port (and then optionally on to a "second fluid reservoir" or sample bottle) after it transitions to a second configuration. ['483 patent, Abstract, 2:14-30, 3:1-20, 5:8-15].

The specification describes an open blood flow path as a state of "fluid communication." Thus, in the first configuration the inlet port is in fluid communication with the first fluid reservoir. In the second configuration the inlet port is in fluid communication with the outlet port, which leads to the sample bottle. The outlet port is "fluidically isolated" from the first fluid reservoir. ['483 patent, Abstract, 2:14-30, 3:1-20; 4:12-18].

The asserted claims of the '483 patent are directed to a "blood sequestration device" and claim this arrangement using various language describing two distinct "flow paths." The first flow path is from the inlet to the first reservoir, and the second flow path is from the inlet to the outlet, thereby "bypassing" the first fluid reservoir and "initial volume of blood sequestered therein." ['483 patent, claims 1, 9, 18, 24].

C. U.S. Patent No. 10,220,139

The '139 patent was filed on February 20, 2018, claiming priority to a non-provisional application filed October 9, 2013. The specification discloses a very different device than the other asserted patents, designed not for obtaining blood

samples but rather for "delivering a fluid to a patient . . . with reduced contamination." ['139 patent, 2:45-47]. Various embodiments of this "fluid transfer device" are "configured to facilitate the insertion of a piercing member . . . into a patient to withdrawal [sic] and isolate a predetermined amount of body fluid from the patient containing, for example, dermally residing microbes." ['139 patent, 5:54-63]. The device then is used to deliver fluids to the patient through the established line. Thus, the '139 patent is directed to a device that is fundamentally different than the accused Kurin Lock device in both design and function. The Kurin Lock is not designed for, and cannot be used for, delivering fluids to a patient.

V. AGREED-UPON CONSTRUCTIONS

A. Preamble Terms That The Parties Agree Are Limiting

Term	Agreed Construction
"An apparatus for obtaining a bodily fluid sample from a patient with reduced contamination" '001 Patent: claims 1, 21	The preamble is limiting.

Term	Agreed Construction
"An apparatus for obtaining biological fluid samples from a patient" '689 Patent: claim 1	The preamble is limiting.

Term	Agreed Construction
"A biological fluid sequestration apparatus configured to be fluidically coupled to a sample vessel" '689 Patent: claim 8	The preamble is limiting.

Term	Agreed Construction
"An apparatus for establishing a sampling flow path substantially free of microbial artifacts between a patient and a sample vessel" '689 Patent: claim 17	The preamble is limiting.

Term	Agreed Construction
"A blood sequestration device" '483 Patent: claims 1, 9, 18, 24	The preamble is limiting.

Term	Agreed Construction
"A bodily fluid sequestration device" '139 Patent: claims 1, 13, 23	The preamble is limiting.

B. Agreed-Upon Constructions (for Terms in the Bodies of the Claims)

Term	Agreed Construction
"blood sequestration device" '483 Patent: claims 1, 9, 18, 24	Plain and ordinary meaning

Term	Agreed Construction
"bodily fluid sequestration device" '139 Patent: claims 1, 13, 23	Plain and ordinary meaning

Term	Agreed Construction
"valve disposed in the first lumen" '139 Patent: claims 1, 13, 23	Plain and ordinary meaning

Term	Agreed Construction
"flow control mechanism" '139 Patent: claims 1, 13, 23, 24	Plain and ordinary meaning

VI. DISPUTED CONSTRUCTIONS

A. "Sequester"

Term	Magnolia's Proposed Construction	Kurin's Proposed Construction
"sequester" (and grammatical variants) '001 Patent: claims 1, 21 '689 Patent: claims 2, 8, 9, 11, 17 '483 Patent: all claims '139 Patent: all claims	Plain and ordinary meaning. If construction is necessary, "to set apart or to segregate."	Original/Answering: "isolate"

1. Plaintiff's Opening Position

An important aspect of the invention in the Magnolia patents is that the initial blood coming out of the patient is treated differently than the subsequent blood used in testing. This is because the first blood to flow through the needle (or IV cannula) is more likely to contain microbes and other contaminants dislodged by the needle or cannula passing through the skin. *See, e.g.*, '001 Patent, 3:38-40. To minimize the contamination risk, the first blood is "sequestered" (*i.e.*, segregated or otherwise set apart) and not used for testing.

The term "sequester" (or a grammatical variant) appears in the claims of all four asserted patents, and in each instance, the term is used consistent with the notion of setting aside an initial portion of blood so the subsequent portion of blood (which is less likely to contain contaminants) is used for testing. *See, e.g.*, '001 Patent, Claim 1 ("*sequestering* in the reservoir contaminants present in the initial volume of bodily fluid, thereby reducing contamination of the subsequent volume of bodily fluid…"); '689 Patent, Claim 2 ("…filling the contaminant reservoir *sequesters* the initial volume of biological fluid…and reduces contamination in the biological fluid flowing to the output tube"); '483 Patent, Claim 1; '139 Patent, Claim 1.

Kurin proposes a narrower interpretation, "isolate," apparently trying to avoid infringement.[5] The term "isolate" does not appear in the body of the '001 and '689 patents. The phrase "fluidically isolate" appears in the '689 patent, but in the claims, it only appears in *dependent* claims that further require that the initial volume of blood be "fluidically isolate[d]" in addition to being sequestered. Independent claim 17, for example, requires a "contaminant reservoir and the junction operable in a second state to (a) *sequester* the first portion of biological fluid in the contaminant reservoir." '689 Patent, Claim 17. Dependent claim 22 further requires that biological fluid to be "*fluidically isolated* in the contaminant reservoir." *Id.*, Claim 22. Similarly, independent claim 1 of the '483 patent requires only that the "initial volume of blood [be] *sequestered*" in the fluid reservoir, while dependent claim 7 adds the requirement that it be "fluidically isolated" in that reservoir. '483 Patent, Claims 1 and 7; *see also id.*, Claims 9 and 14, 18 and 23, 24 and 28; '139 Patent, Claims 1 and 2, 13 and 15, 23 and 24. Because "[u]nder the doctrine of claim differentiation, dependent claims are presumed to be of narrower scope than the independent claims from which they depend," *AK Steel Corp. v. Sollac & Ugine,* 344 F.3d 1234, 1242 (Fed. Cir. 2003), and because "[w]hen different words or phrases are used in separate claims, a

[5] Kurin's original construction of "sequester" was "to isolate ***with a physical barrier***." JA0012-15 (Kurin's Oct. 9, 2019 Letter). In the Joint Claim Construction Chart, Kurin dropped "with a physical barrier."

difference in meaning is presumed," *Nystrom v. TREX Co.*, 424 F.3d 1136, 1143 (Fed. Cir. 2005), Kurin's proposed construction should be rejected.

2. Defendant's Answering Position

The term "sequester" is found in nearly every asserted independent claim, but the "thing" that must be sequestered is not always the same. Some claims require sequestration of the "contaminants present in the initial volume of bodily fluid" (*see, e.g.*, '001 claim 1) while others require sequestration of the "initial volume of bodily fluid." (*see, e.g.*, '001, claim 21).

Starting as we must with the plain meaning, the easiest to understand synonym of "sequester" is the straight-forward synonym "isolate." *See* JA0350 (Oxford Dictionary of English, 3rd Ed. (2010)) (defining "sequester" as "isolate or hide away"). This reflects common usage and understanding of the term "sequester," which is perhaps most commonly associated with sequestration of a jury. As the future members of the jury in this matter may know (and will be relieved that it does apply to them), jury sequestration refers to the practice of isolating jurors from their families, the general public, and the media to avoid outside influence on their consideration of a case.

This plain and ordinary meaning is fully supported by the intrinsic evidence. The '001/'689 specification uses the term "sequester" just once, describing a study wherein certain patients "had an initial volume of drawn blood sequestered into a

pre-sample reservoir." ['001/'689 patents, 10:3-33]. This test used the "single blood flow path" method, so the blood was "sequestered" in its own bottle and thus isolated from the rest of the system.

Magnolia proposes that "sequester" be given its plain and ordinary meaning, yet objects to "isolate" claiming that it is a "narrower interpretation." Magnolia never explains how "isolate" is narrower than "sequester," and instead immediately moves to a claim differentiation argument.

Magnolia's claim differentiation argument actually confirms that "isolate" is the best construction of "sequester." Magnolia asserts that the use of the term "fluidically isolate" in some dependent claims indicates that "isolate" and "sequester" must have different meanings. Claim differentiation, however, does not apply here, as there would be no conflict construing the term "sequester" in the relevant independent claims to mean "isolate."

The term "fluidically isolate" used in the dependent claims cited by Magnolia is not the same as "isolate." The word "fluidically" modifies "isolate," so "fluidically isolate" refers to one form of isolation and is inherently narrower than "isolate" alone. Thus, reading the term "sequester" in the relevant independent claims to mean "isolate" would not cause the dependent claims to have the same scope, as the dependent claims impose a further requirement that such isolation be "fluidic" isolation. *See Tandon Corp. v. U.S. Int'l Trade*

Comm'n, 831 F.2d 1017, 1023 (Fed. Cir. 1987) ("There is presumed to be a difference in meaning and scope when different words or phrases are used in separate claims. To the extent that the absence of such difference in meaning and scope would make a claim superfluous, the doctrine of claim differentiation states the presumption that the difference between claims is significant.")

The intrinsic evidence confirms this understanding. The term "fluidic isolation" is always used in contrapose with the term "fluidic communication," appearing only in claims depending from independent claims that require "fluidic communication" among certain components.[6] Moreover, the specification of the '139 patent explains that in some embodiments the "fluid transfer device is fluidically isolated from the fluid reservoir ***to sequester*** the predetermined volume of bodily fluid in the fluid reservoir." ['139 patent, Fig. 40, 5:10-12, 29:36-40]. Thus, fluidic isolation is being used to describe one way to "sequester" the initial bodily fluids.

Magnolia offers nothing to support its alternative proposal that sequester be construed to mean "to set apart or to segregate." Neither is as close a synonym as "isolate," which matches the plain and ordinary meaning of "sequester." Sequester and isolate are synonyms, equal in scope, yet isolate is more easily understood by a

[6] The term "fluidic isolation" also appears extensively in the claims of the '689 patent, though it is not used in the '689 specification and appears to be a term that Magnolia began using long after the '689 specification was drafted in 2007.

jury. For this reason, and because it is best supported by the intrinsic evidence, Kurin respectfully requests that the Court construe "sequester" to mean "isolate."

3. Plaintiff's Reply Position

Kurin wants to replace the word the inventors chose to use in their claims (sequester) with a different word (isolate). It offers a three-step argument that fails at each step.

First, it assumes (wrongly) that the law permits substitution when two words are synonyms (it doesn't). Second, it posits that its word is a "straight-forward synonym" for the inventor's word (it isn't). Kurin Answering Br. at 20. Third, it speculates that its word is "more easily understood by the jury" (it isn't, and Kurin's focus invites legal error). *Id.* at 23.

The Federal Circuit long-ago rejected the idea that a party could merely replace a word in the claim with a synonym under the guise of claim construction.[7] In *International Rectifier Corp. v. IXYS Corp.*, 361 F.3d 1363, 1374 (Fed. Cir. 2004), the Federal Circuit criticized the district court's use of a dictionary definition of a synonym for the claim term, rather than the claim term itself.

> [T]he district court's adoption of a definition attributed to "adjacent," a synonym of the claim term, disregards entirely the distinction between the two terms set forth in the usage note. Had the inventor meant "adjacent," he could have used that word. However, we must consider the word that the inventor actually chose and use the definitions of that term that are consistent with the written description.

[7] Kurin does not cite a single case in favor of its synonym-substitution argument.

Int'l Rectifier, 361 F.3d at 1374. Similarly, in *C.R. Bard, Inc. v. U.S. Surgical Corp.*, 388 F.3d 858, 863 (Fed. Cir. 2004), the Federal Circuit explained that synonyms provided by dictionaries were "largely unhelpful" and recognized "that merely rephrasing or paraphrasing the plain language of a claim by substituting synonyms does not represent genuine claim construction." *Bard*, 388 F.3d at 863. Thus, even if "sequester" and "isolate" were "straight-forward synonyms," as Kurin alleges, it would still be legal error to substitute one for the other under the guise of claim construction.

In any event, "sequester" and "isolate" are not synonyms. Kurin quotes the '139 patent and concludes "fluidic isolation is being used to describe *one way* to 'sequester' the initial bodily fluids."[8] Kurin Answering Br. at 22-23. If isolation (or even fluidic isolation) is but *one way* of sequestering fluids, the words are not synonyms. Even if isolation is broader than fluidic isolation, the intrinsic evidence conclusively shows that "isolate" does not span the same scope as "sequester."

Kurin cites the *Tandon* case to remind the Court of the presumption created by the doctrine of claim differentiation. Kurin Answering Br. at 22. Where Kurin errs is in its assumption that the claim differentiation argument favors Kurin over Magnolia. It does not.

[8] Unless otherwise noted, all emphasis is added.

Kurin overlooks the fundamental point that the patentee knew of the word "isolate" (and in fact used that word in various dependent claims), but instead chose to use "sequester" in the independent claims. There is no reason to construe "sequester" with the narrower interpretation of "isolate" when the patentee knew how to use "isolate" but chose "sequester."

The final step in Kurin's argument is its unsupported assumption that "isolate" will be more easily understood by the jury than "sequester." What Kurin misses is that the legal inquiry is not what a term's plain and ordinary meaning is to a lay person, but what its meaning is to a skilled artisan. "Claim terms must be construed as they would be understood by a person of ordinary skill in the art to which the invention pertains. *Specialty Composites v. Cabot Corp.,* 845 F.2d 981, 986 (Fed. Cir. 1988). What the claim term would mean to a layman is legally irrelevant." *Searfoss v. Pioneer Consol. Corp.*, 374 F.3d 1142, 1149 (Fed. Cir. 1988).

"Sequester" is a well-known term to those of skill in the art. Kurin itself has marketed and sold its accused device (called the Kurin Lock) as a *sequestration* device. JA0016 (MAG-DEL0000663) at JA0019 (MAG-DEL0000666) ("The Kurin blood capture device *sequesters* the initial draw of blood upon initial venipuncture.") & JA0024 (MAG-DEL0000671) at JA0030 (MAG-DEL0000677) ("[T]he Kurin blood lock mechanism *sequesters* the initial sample of blood . . . .").

Its own patents are titled "Blood Contaminant *Sequestration* Device" and consistently use the word "sequester." *See, e.g.*, U.S. Patent Nos. 9,820,682 ("Blood Sample Optimization System and Blood Contaminant Sequestration Device and Method"), 10,010,282 (same), 10,143,412 (same).

The consistent use of "sequester" (and not "isolate") by both Magnolia and Kurin demonstrates that the skilled artisan readily understands the word. The ability of the skilled artisan to understand "sequester" is even more apparent when its usage is considered in the context of the remaining claim language and the specifications of the Magnolia patents. Both the claim language and the patent specifications recite and teach that it is an initial volume of bodily fluid that is sequestered and the subsequent volume of bodily fluid that is not sequestered. *See e.g.*, '001 Patent, Claim 1. Nothing more is necessary.

4. Defendant's Sur-Reply Position

It is entirely appropriate to construe a term to clarify it for the jury. The plain meaning of a term is as a person of ordinary skill would have understood it, "but that is no reason why a claim term cannot be given a construction that explains, in language comprehensible to a jury, what the term means to a person of ordinary skill." *Largan Precision Co, Ltd v. Genius Elec. Optical Co.*, No. 13-CV-02502-JD, 2014 WL 5358426, at *4 (N.D. Cal. Oct. 20, 2014). "After all, … claim terms written in technical language may have to be recast in words that non-

experts will understand." *Id.* (citing *Abbott Laboratories v. Sandoz, Inc.*, 544 F.3d 1341, 1360 (Fed. Cir. 2008) ("[C]laims are construed as an aid to the decision-maker, by restating the claims in non-technical terms.")); *see also Power–One, Inc. v. Artesyn Techs., Inc.*, 599 F.3d 1343, 1348 (Fed. Cir. 2010) ("The terms, as construed by the court, must 'ensure that the jury fully understands the court's claim construction rulings and what the patentee covered by the claims.'")

Here, the Court should construe "sequester" as its more easily understood synonym "isolate." *Cf. Asia Vital Components Co. v. Asetek Danmark A/S*, No. 16-CV-07160-JST, 2018 WL 452109, at *7 (N.D. Cal. Jan. 17, 2018) (construing "separably" as "detachably" to "provide clarity to the jury"); *SkinMedica, Inc. v. Histogen Inc.*, No. 09-CV-122 JLS NLS, 2011 WL 2066619, at *10 (S.D. Cal. May 24, 2011) (construing "substantially enveloping" to mean "substantially enclosing, surrounding, or covering"). Magnolia's citations do not support its argument that use of synonyms is error. In *International Rectifier Corp. v. IXYS Corp.*, 361 F.3d 1363, 1373-74 (Fed. Cir. 2004), the error was not the use of a synonym, but rather disregarding a "distinction between the two [purportedly synonymous] terms". In *C.R. Bard, Inc. v. U.S. Surgical Corp.*, 388 F.3d 858, 863 (Fed. Cir. 2004), dictionary definitions were "largely unhelpful" because the intrinsic evidence required a particular construction, and the statement that

rephrasing "does not represent genuine claim construction" was not the basis for decision. *See id.*

Magnolia offers no basis to differentiate "sequester" and "isolate." But, Magnolia admitted that "sequester" and "*fluidic* isolation" are not synonyms, *supra*, p. 24, effectively nullifying its claim differentiation argument, *supra*, pp. 18-19. Construing the term "sequester" to mean "isolate" will help jurors understand and apply the claims.

B. "Initial Volume" Terms

Term	Magnolia's Proposed Construction	Kurin's Proposed Construction
"initial volume" terms '001 Patent: claims 1, 4, 21-23 ("initial volume of bodily fluid") '689 Patent: claims 1, 2, 6 ("initial volume of biological fluid"); claims 8, 11, 13, 15, 17 ("first portion of biological fluid") '483 Patent: claims 1, 8, 9, 18, 19, 21, 24	Plain and ordinary meaning	Original/Answering: "All of the fluid that flows before a transition" (in all of the various ways a transition is claimed)[9]

[9] Magnolia's view is that Kurin changed its original proposed construction. *Compare* D.I. 48-1 at 4 ("all of the fluid that flows before a transition, *in all of the various ways a transition is claimed*") *with* Kurin Answering Br. at 31 ("all of the fluid that flows before a transition"). Kurin disagrees.

("initial volume of blood") '139 Patent: claims 1, 13, 19, 23, 27 ("initial volume of bodily fluid")		

1. Plaintiff's Opening Position

"Initial volume" is the term the claims use to describe the fluid that is received by the reservoir, and therefore not used for testing.

The two words that form this limitation, "initial" and "volume," are common and well-understood by the skilled artisan. As the claims and specifications of the asserted patents explain, "[p]rior to withdrawing bodily fluid into the one or more sample vessels for incubation, an *initial volume* of withdrawn bodily fluid is placed in one or more pre-sample reservoirs and is not used for the incubation in culture media." '001 Patent, 3:4-8; *see also id.*, Claim 1 ("a reservoir configured to receive an *initial volume* of bodily fluid withdrawn from the patient"); '689 Patent, Claim 1; '483 Patent, Claim 1; '139 Patent, Claim 1.

Kurin's construction, with its repeated use of "all of" ("***all of*** the fluid that flows before a transition, in ***all of*** the various ways a transition is claimed"), improperly narrows the claims. *Thorner v. Sony Comput. Entm't Am. LLC*, 669 F.3d 1362, 1366-67 (Fed. Cir. 2012). Kurin also, wrongly, imports an ambiguous, nineteen-word phrase to replace the simple two-word phrase ("initial volume").

See Am. Patent Development, Corp. v. Movielink, LLC, 604 F. Supp. 2d 704, 716 (D. Del. 2009) (rejecting a construction that "is merely a verbose paraphrasing of the claim language that otherwise offers little to assist one of skill in the art in understanding the claims").

Moreover, Kurin's construction violates the doctrine of claim differentiation. Dependent claim 6 of the '689 Patent recites: "The apparatus of claim 1, wherein ***all of*** the initial volume of the biological fluid from the patient flows into the contaminant reservoir." *See also* '689 Patent, Claims 15, 21, 28. "[T]he presence of a dependent claim that adds a particular limitation raises a presumption that the limitation in question is not found in the independent claim." *Liebel-Flarsheim Co. v. Medrad, Inc.*, 358 F.3d 898, 910 (Fed. Cir. 2004).

2. Defendant's Answering Position

The asserted patents use the term "initial volume of bodily fluid/blood"[10] to refer to the initial portion of blood removed from the patient and sequestered so that a clean blood sample can be taken. Every disclosed embodiment and every asserted claim requires a transition once the "initial volume of bodily fluid/blood" has been withdrawn from the patient and/or placed into the reservoir. ['001 patent, Abstract, 2:64-3:9, 5:35-6:27, 7:27-43, 7:49-8:16, 8:28-9:15, claims 1, 21; '689

[10] Or, in the '689 patent, the terms "first portion of biological fluid" and "initial volume of biological fluid."

patent, Abstract, 2:66-3:10, 5:36-6:28, 7:28-44, 7:50-8:17, 8:29-9:15, claims 1, 8, 17, 23; '483 patent, 2:25-30, 3:13-38, 4:3-18, 5:39-6:56, 7:50-56, 13:41-14:8, 19:1-5, claims 1, 9, 18, 24; '139 patent, 4:56-5:15, 7:50-8:8, 8:41-56, 9:30-10:13, 13:1-6, 13:43-61, 15:58-16:28, 18:53-59, 19:46-59, 20:2-7, 22:20-26, 22:49-23:3, 23:52-58, 25:23-26, 25:54-67, 26:14-19, 28:9-12, 28:44-54, 29:16-65, claims 1, 13, 23].

This transition is variously claimed as being from one "operating mode" to another, from one "configuration" to another, from one "state" to another, etc., and in some embodiments this transition occurs "automatically" while in others it is done "manually." In every instance the "initial volume" of bodily fluid that is being sequestered is differentiated from the "subsequent volume" (or from a fluid flow received or able to be received, in the '139 patent) by this transition, and all of the "bodily fluid/blood" prior to the transition constitutes the "initial volume." [*Id.*].

Kurin does not seek a "nineteen-word" construction paraphrasing the claim language. Rather, it seeks to properly construe the scope of the term "initial volume" in light of the specification, which directly and consistently links it to the transition from a first state to a second state. The specific construction sought is that "initial volume" means "all of the fluid that flows before a transition." This is exactly what is described in the specification.

Magnolia first asserts that it seeks the "plain meaning" of this term, but the plain meaning of "initial volume" ***requires*** context. Something can only be "initial" with respect to something else, so a proper construction must answer the question "initial with respect to what?" Without this context, these claims are fatally indefinite.

Magnolia offers only a quotation from the general description in the '001 specification that "[p]rior to withdrawing bodily fluid into the one or more sample vessels for incubation, an *initial volume* of withdrawn bodily fluid is placed in one or more pre-sample reservoirs and is not used for the incubation in culture media." *Supra*, p. 29. Yet, in Magnolia's own example, the event that delineates between the "initial volume" of bodily fluid that is sequestered and the subsequent volume of bodily fluid for the sample is the claimed "transition from the first operating mode to the second operating mode." ['001 patent, 11:25-30].

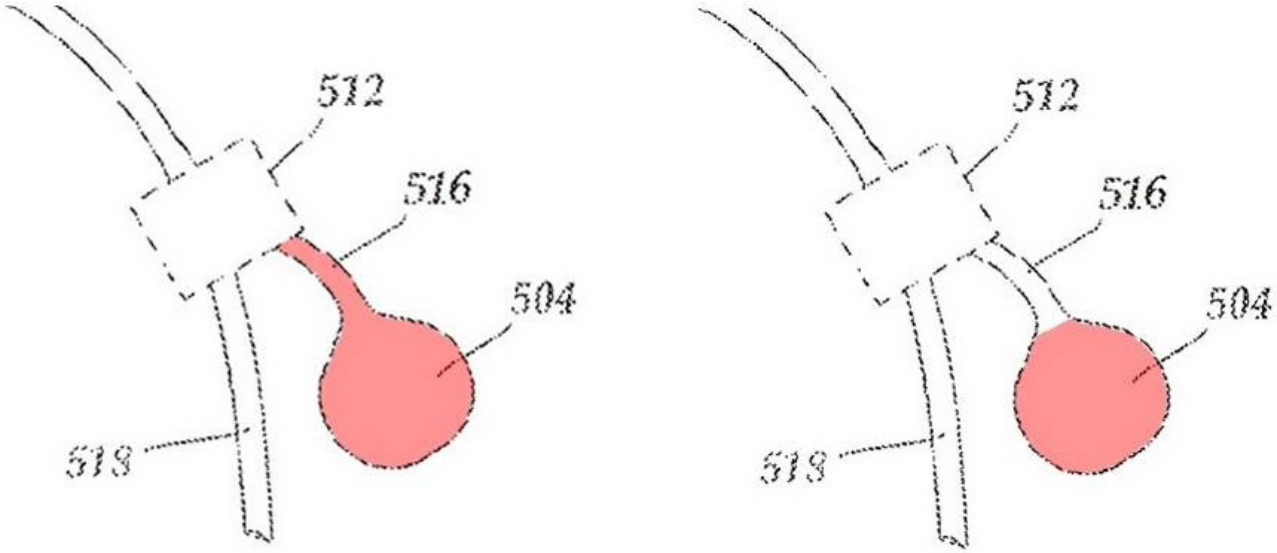
Magnolia's claim differentiation argument based on claim 6 of the '689 patent is misplaced. Claim 6 of the '689 patent depends from claim 1, which requires:

> the junction operable to allow an ***initial volume of biological fluid*** to flow from the patient to the contaminant 20 reservoir, and to **transition** as a direct result of filling the contaminant reservoir **to allow a subsequent volume of biological fluid to flow** from the inlet to the second outlet.

['689 patent, 11:19-24]. Claim 1 further requires that the junction have a "first outlet" that is "fluidically coupled" to the "contaminant reservoir." ['689 patent, 11:15-16]. Consistent with this claim 1, the "initial volume" of fluid might occupy not just the contaminant reservoir, but also any connecting flow path between the contaminant reservoir and the "first outlet."

Claim 6 imposes a further requirement that "***all*** of the initial 40 volume of the biological fluid from the patient flows into the contaminant reservoir." This simply requires that none of the initial volume remain in any connecting tube or line between the first outlet of the junction and the reservoir. This limitation in claim 6 is not inconsistent with Kurin's proposed construction; it is simply a narrowing dependent claim.

The following cropped portions of Fig. 5 of the '689 patent have been annotated to illustrate this distinction. As described in the specification, "diversion mechanism 512" is a "black box" that contains the junction. [*See* '689 patent, 7:8-10]. The figure on the left shows (in red added by Kurin) bodily fluid occupying the contaminant reservoir ("pre-sample reservoir 504") *and* "first sterile output tubing 516" ['689 patent, 7:8-16], illustrating a possibility covered by claim 1. The figure on the right shows (again in red added by Kurin) bodily fluid occupying *only* the contaminant reservoir, illustrating the narrower possibility covered by claim 6.



Portion of '689 patent, Fig. 5 (annotated)

Kurin's construction clarifies that – consistent with the claim language – "initial volume" means all of the fluid that flows before the "transition." This limitation is broader than dependent claim 6 of the '689 patent, which requires "all of the initial volume" to flow into the "contaminant reservoir." *See World Class Tech. Corp. v. Ormco Corp.*, 769 F.3d 1120, 1125 (Fed. Cir. 2014) (holding claim differentiation does not apply when construction does not give independent claim "the same scope" as dependent claim).

Kurin's construction does not improperly narrow the claims by importing "limitations from the specification into claims." *See Thorner v. Sony Computer Entm't Am. LLC*, 669 F.3d 1362, 1366–67 (Fed. Cir. 2012). The term "initial volume" can ***only*** be understood in the context of what the "volume" is "initial" with respect to. The claims make clear that the "volume" must be the entire

volume "initial" to the particular transition that is described in each relevant claim. Kurin's proposed construction does not import any limitation, it simply clarifies for the jury "what the patentee covered by the claims." *See O2 Micro Int'l Ltd. v. Beyond Innovation Tech. Co.*, 521 F.3d 1351, 1362 (Fed. Cir. 2008).

3. Plaintiff's Reply Position

Kurin implicitly concedes that its original 19-word proposal was unsupported and overreaching. In its Answering Brief, it drops, without explanation, over half of what it originally asked for. *Compare* D.I. 48-1 at 4 ("all of the fluid that flows before a transition, *in all of the various ways a transition is claimed*") *with* Kurin Answering Br. at 31 ("all of the fluid that flows before a transition").

Kurin's problem is that what remains fares no better than what it dropped. It still seeks a construction that replaces two common and well-understood words, "initial" and "volume," with a still-ambiguous and still-improperly-narrowing proposal that imports multiple limitations ("all of the fluid" and "before a transition") wholly unsupported by the claim language or the specification.

The black letter law of claim differentiation is "dependent claims are presumed to be of narrower scope than the independent claims from which they depend." *AK Steel Corp. v. Sollac & Ugine*, 344 F.3d 1234, 1242 (Fed. Cir. 2003). Kurin defies this rule by injecting "all" in its construction for independent claim

terms when the patentee expressly used "all" in the dependent claim terms. *See* '689 Patent, Claims 6, 15, 21, 28. The patentee claimed an "initial volume of bodily fluid" in the independent claim. *See, e.g.*, '001 Patent, Claim 1. The patentee did not claim *all* of the bodily fluid but rather just an *initial volume* of bodily fluid.

The Federal Circuit has cautioned against inserting words like "all" into claim language. *See U.S. Ethernet Innovations, LLC v. Acer, Inc.*, 646 F. App'x 929, 934 (Fed. Cir. 2016) (rejecting constructions of "store *all* the data of frames" or "store entire frames of data" because the "claims say only 'data of frames,' indicating that the buffer need not be capable of storing an entire Ethernet frame of data"). By including the words "all," Kurin appears to be proposing a stricter requirement (e.g., a numerical limitation) than the claim requires. But "[i]t is usually incorrect to read numerical precision into a claim from which it is absent, particularly when other claims contain the numerical limitation." *Modine Mfg. Co. v. U.S. Int'l Trade Comm'n*, 75 F.3d 1545, 1551 (Fed. Cir. 1996).

The claim language itself clearly describes the "initial volume" as the volume of fluid received by the reservoir, not "all of the fluid that flows before a transition." *See, e.g.*, '001 Patent, Claim 1 ("a reservoir configured to receive an *initial volume* of bodily fluid withdrawn from the patient"); '689 Patent, Claim 1; '483 Patent, Claim 1; '139 Patent, Claim 1. Kurin wrongly contends that "[e]very

disclosed embodiment and every asserted claim requires a transition . . . ." Kurin Answering Br. at 31. In fact, many of the asserted claims do not claim a "transition." *See* '001 Patent, Claim 21; '483 Patent, Claim 1; '139 Patent, Claims 1, 13, 23.

In *Teleflex, Inc. v. Ficosa North America Corp.*, 299 F.3d 1313, 1327-28 (Fed. Cir. 2002), the Federal Circuit cautioned against the approach Kurin proposes. In that case, the district court improperly construed "clip" to mean "a single pair of legs" despite the fact that "[n]either 'single' nor 'pair of legs' appears in claim 1." *Id.* Even though "[t]he specification describes only one embodiment of the claimed 'clip (28),' . . . the record is devoid of 'clear statements of scope' limiting the term appearing in claim 1 to having 'a single pair of legs.'" *Id.* at 1328.

In this case, "all" does not appear in a single independent claim under construction. Further, similar to the *Teleflex* case, the '483 specification at issue here teaches at least one embodiment which does not recite that a "transition" occurs. *See, e.g.*, '483 Patent, 3:21-29 ("[A] bodily-fluid transfer device can be configured to selectively divert a first, predetermined amount of a flow of a bodily-fluid to a first fluid reservoir before permitting the flow of a second amount of the bodily-fluid into a second fluid reservoir."). And on the question of whether "all of" the fluid removed from the patient must be sequestered, the specification is, at

best, silent. *See, e.g.*, *id.*, 3:66-67 ("the term 'first amount' does not explicitly describe a predetermined amount"); '001 Patent, 3:5-7 (simply "an initial volume of withdrawn bodily fluid is placed in one or more pre-sample reservoirs").

Moreover, Magnolia never disavowed any claim scope with respect to "initial volume," hence the embodiments do not limit the scope of the term either. "Our case law is clear that an applicant is not required to describe in the specification every conceivable and possible future embodiment of his invention." *Rexnord Corp. v. Laitram Corp.*, 274 F.3d 1336, 1344 (Fed. Cir. 2001).

Kurin's reliance on *World Class* is inapposite because, even if claim 6 had independent significance from claim 1, it still would not provide authority for narrowly rewriting the claim language with the word "all." The specification never describes the "initial volume" as yielding every single drop of fluid before a certain event. *See* '689 Patent, 3:6-10, 10:18-33. So it is improper to interpret "initial volume" as "all" of something regardless of whether the presumption of claim differentiation applies. *Kaneka Corp. v. Xiamen Kingdomway Grp. Co.*, 790 F.3d 1298, 1307 (Fed. Cir. 2015) (concluding that it was error to construe the term "oxidizing" as requiring "all or substantially all" of the material to be oxidized).

To the extent that "initial volume" needs context, it is provided by the claims' additional requirement of a "subsequent volume." *See, e.g.*, '001 Patent, Claims 1, 21; '689 Patent, Claims 1, 23; '483 Patent, Claims 1, 9, 18, 24.

Tellingly, Kurin does not think that "subsequent volume" needs construction, ergo neither should "initial volume."

4. Defendant's Sur-Reply Position

Magnolia's proposed plain meaning of "initial volume" would leave jurors with unresolved question including: (i) initial in relation to what event?, and (ii) how much is the volume? Recitation of a "subsequent volume" does not answer these questions; something must delineate between the two volumes. In each asserted claim this line is marked by a transition, and therefore "initial volume" means "all of the fluid that flows before [that] transition."

Kurin included the phrase "in all the various ways a transition is claimed" to acknowledge that some claims do not use the term "transition." Yet, in every asserted claim, a transition occurs at the point when flow of the initial volume is complete: *i.e.*, when "all of the fluid that flows before [the] transition" has flowed. This is entirely consistent with the passages from the specifications Magnolia cites. *See supra*, pp. 37-38.

The cases cited by Magnolia do not apply. Kurin is not improperly narrowing the claims based on the specification, as *in U.S. Ethernet Innovations, LLC v. Acer, Inc.*, 646 F. App'x 929, 933-34 (Fed. Cir. 2016), is not importing an embodiment, as in *Teleflex, Inc. v. Ficosa North America Corp.*, 299 F.3d 1313, 1327-28 (Fed. Cir. 2002), seeks to import no numerical limitation from the

specification or other claims, as in *Modine Mfg. Co. v. U.S. Int'l Trade Comm'n*, 75 F.3d 1545, 1551 (Fed. Cir. 1996), and is not seeking include the term "all" without support, as in *Kaneka Corp. v. Xiamen Kingdomway Grp. Co.*, 790 F.3d 1298, 1307 (Fed. Cir. 2015). Kurin's construction simply clarifies what is the claimed "initial volume" consistent with the specifications.

C. "Diverter"

Term	Magnolia's Proposed Construction	Kurin's Proposed Construction
"diverter" '001 Patent: claims 1, 21, 28 '689 Patent: claim 23 (no longer asserted per Magnolia's Reply Position)	Plain and ordinary meaning. If construction is necessary, "a component with an inlet and two outlet branches for directing the flow of fluid."	Original: Means-plus-function Function: The function of the "diverter" is to direct fluid flow to one fluid flow path or to a second fluid flow path. Structure: The structure of the "diverter" is disclosed in the '001 patent's specification at 7:49-9:15 and in Figs. 6A, 6B, 7A, 7B. The structure of the "diverter" is disclosed in the '689 patent's specification at 7:50-9:15 and in Figs. 6A, 6B, 7A, 7B.

		In the alternative, if not held to be a means-plus-function term, "diverter" should be construed to mean "mechanism that can be moved to redirect fluid from one path to another path." Answering: Means-plus-function or "a mechanism that directs flow down a specific path.[11]

1. Plaintiff's Opening Position

A diverter, quite simply, facilitates diversion. In the context of the '001 and '689 patents, the claimed "diverter" diverts (*i.e.*, directs) bodily fluid down a first path (toward a pre-sample reservoir) or a second path (toward a sample vessel). The specific structure of the diverter is defined in the claims themselves. For example:

- "diverter ha[s] an inlet, a first outlet in fluid communication with the reservoir, and a second outlet" ('001 Patent, Claim 1)
- "the diverter includ[es] an inlet, an outlet, and a reservoir configured to receive an initial volume of bodily fluid withdrawn from the patient" ('001 Patent, Claim 21)

[11] This is a simplification of the proposed alternative construction from the original presented by Kurin in the joint claim construction chart.

- "the "diverter includ[es] a reservoir and a junction configured to control fluid flow from the patient" ('689 Patent, Claim 23)

In all instances, the claimed diverter is a component with an inlet and two outlet branches for directing the flow of fluid down a first or second path.[12] Thus, one of skill in the art would understand this to be the plain and ordinary meaning of the term.

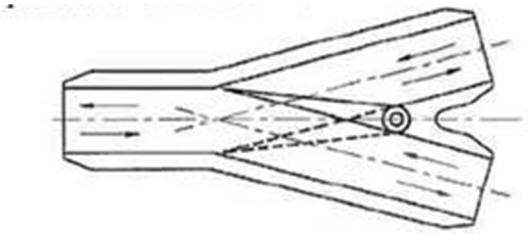
Kurin's backup construction, which requires that the diverter be a mechanism that "can be moved" to do its job of directing fluid from one path to another, improperly reads into the claims a limitation from the specification, in direct violation of *Phillips*.[13] *Phillips v. AWH Corp.*, 415 F.3d 1303 (Fed. Cir. 2005) (en banc). Nowhere in the specification or file histories did the patentees define diverter to require a movable mechanism, nor did the patentees disavow the full scope of the term as claimed. *See, e.g.*, '001 Patent, 7:7-26, 7:33-43, 7:49-54,

[12] For this reason alone, Kurin's proposed means-plus-function construction fails. Where, as here, the claim "recit[es] sufficient structure for performing th[e recited] function," the term is not subject to section 112, ¶ 6 because the presumption flowing from the absence of the term "means" is not overcome. *Williamson v. Citrix Online, LLC*, 792 F.3d 1339, 1348 (Fed. Cir. 2015).

[13] Further highlighting the flawed logic of Kurin's proposed constructions, Kurin has proposed that four claim terms at issue ("diverter," "junction," "blood sequestration device" and "bodily sequestration device") be construed the exact same way, notwithstanding the fact that they are different terms, that two of the terms ("diverter" and "junction") both appear in the same claim ('689 Patent, Claim 23), and that the other two terms are from two unrelated patent families.

Figs. 5-7. The specification makes clear that "many different types of diversion mechanisms can be used to divert the flow of bodily fluids from a patient," supporting the plain and ordinary meaning construction proposed by Magnolia. '001 Patent, 7:49-50; *see also id.*, 6:60-65, 7:37-43.

Moreover, one of skill in the art would have understood that the claimed diverter need not include moving parts to perform its claimed function of diverting fluid. First, at the time of the invention, the general principle and structure of diverters for fluid control systems were well known:



Principle of Diverter

JA0100-103 ("The Pipeline Pigging Handbook (3rd edition, 2003)); *see* JA0042-43 (Decl. of Dr. Juan Santiago ("Santiago Declaration")) ¶ 21. Second, it was well known that diverters (also referred to as "diverter valves") may or may not include moving components. JA0043-45 (Santiago Decl.) ¶ 22. The "fluidic diverter valve," shown in Figure 7 below, is an example of a "standard planar no-moving-part fluidic valve" from the relevant time period. JA0105-116 (Tesar, Fluidic Valves for Variable-Configuration Gas Treatment, 83 Engineering Research and Design 1111, 1114 (2005)). As explained in the Tesar paper, "[f]luidic no-

moving-part valves" were known to be an "inexpensive and robust [and] attractive alternative" to "mechanical diverter valves" (*e.g.*, Figures 6 and 7):

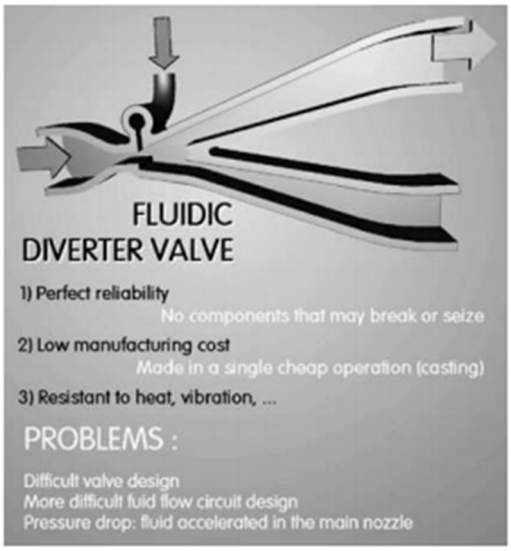


Figure 7. An example of standard planar no-moving-part fluidic valve, its advantages and problem areas.

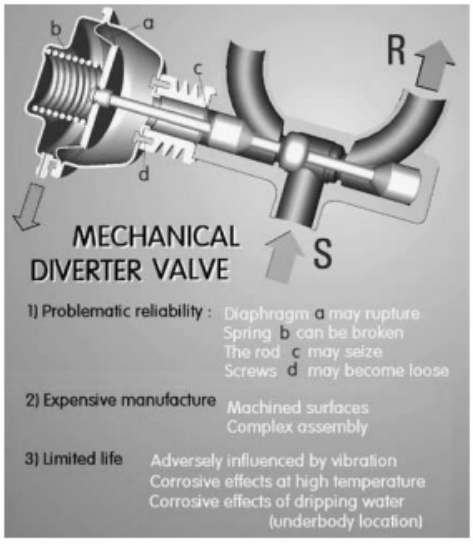


Figure 6. An example of typical mechanical valve currently considered for the variable configuration aftertreatment systems—and its disadvantages, making it the weakest link in existing proposals.

JA0106, JA0109 (Tesar), 1111, 1114; JA0043-45 (Santiago Decl.) ¶ 22. Finally, these well-known diverter/diverter valve concepts requiring no moving components were known to apply broadly across mechanical engineering disciplines, including biomedical engineering. JA0045-47 (Santiago Decl.) ¶¶ 23-24. As an example from the relevant time period, a 2007 publication co-authored by researchers from the Department of Bioengineering at UC Berkeley describes capillary burst valves, which utilize the geometry of the valve and capillary action to direct fluid flow:

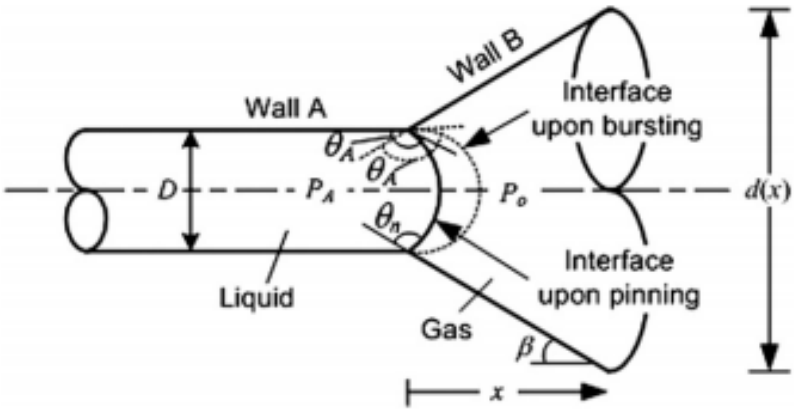


Fig. 1. Capillary burst valve in a round tube.

JA0131-137 (Cho, *How the Capillary Burst Microvalve Works*, J. Colloid & Interface Sci. 306, 380 (2007)); JA0045-47 (Santiago Decl.) ¶ 24. As such, one of skill in the art would not have understood the claimed "diverter" to require moving parts, as Kurin proposes.

Finally, even if the Court were to consider Kurin's means-plus-function proposal, Kurin failed to provide a rational proposal as to structure. Kurin's citation to 1.5 columns and 4 figures of alleged structure impermissibly incorporates structure from the written description beyond that necessary to perform the claimed function. *Asyst Techs., Inc. v. Empak, Inc.*, 268 F.3d 1364, 1370 (Fed. Cir. 2001).

2. Defendant's Answering Position

All of the limitations in the asserted claims requiring a "diverter" are properly considered "means-plus-function" claims. These claims do not include the word "means," but the presumption that a claim without the word "means" is

not means-plus-function is overcome if "the claim term fails to recite sufficiently definite structure or else recites function ***without reciting sufficient structure for performing that function***." *Williamson v. Citrix Online, LLC*, 792 F.3d 1339, 1349 (Fed. Cir. 2015) (quotations omitted). Rebutting this presumption does not require a showing that the limitation is "devoid of anything that can be construed as structure." *Id.*

Here, the asserted claims consistently describe the "diverter" in primarily functional language. *See MTD Prod. Inc. v. Iancu*, 933 F.3d 1336, 1343 (Fed. Cir. 2019) ("[C]laim language reciting what [a claimed element] is 'configured to' do is functional."). For example, claim 23 of the '689 patent requires "a diverter including a reservoir and a junction ***configured to control fluid flow from the patient***, the junction including an inlet fluidically coupled to the input tube, a first outlet fluidically coupled to the reservoir, and a second outlet fluidically coupled to an output tube." ['689 patent, 13:4-8]. At its core, this limitation recites a function – the "diverter" must be "configured to control fluid flow from the patient."

While the claim recites some related structure – a reservoir, a junction, an inlet, and two outlets – this structure is not sufficient to perform the claimed function of controlling fluid flow from the patient. A "reservoir" does not control fluid flow and the claimed "junction" having an inlet and two outlets just defines possible fluid flow paths. Nothing in this claimed structure is sufficient to perform

the claimed function of ***controlling fluid flow*** or as Magnolia puts it diverting "bodily fluid down a first path." *Supra*, p. 41.

As explained in the specification, the function of controlling fluid flow is performed by a "diversion mechanism." ['001 patent, 6:60-65, 7:33-43; '689 patent, 6:61-66, 7:34-44]. The specification then describes two possible structures that can perform this function of controlling fluid flow: (i) a switchable valve, or (ii) flow control blocks. ['001 patent, 7:50-9:15; '689 patent, 7:51-9:15]. *See Cross Med. Prod., Inc. v. Medtronic Sofamor Danek, Inc.*, 424 F.3d 1293, 1307–08 (Fed. Cir. 2005) (holding a claim limitation was means-plus-function because more than the claimed structure was required to perform the claimed function). Those are examples of structure sufficient to perform the claimed function, but they are not claimed. Absent some such structure, the claims simply identify a function to be performed – controlling fluid flow.

The asserted claims alone do not recite sufficient structure to perform this claimed function, and thus should properly be construed as "means-plus-function" claims. The only two structures disclosed in the specification for performing that claimed function are a "switchable valve" and "flow control blocks." Thus, the scope of the term diverter is properly limited to those two structures and their equivalents. ['001 patent, 7:50-9:15; '689 patent, 7:51-9:15]. *See Callicrate v. Wadsworth Mfg., Inc.*, 427 F.3d 1361, 1369 (Fed. Cir. 2005) (construction must

properly account for "all structures in the specification corresponding to the claimed function.")

If this Court determines that "diverter" is not a means-plus-function limitation in any of the asserted claims, Kurin proposes that the claim term "diverter" be construed as: "a mechanism that directs fluid flow down a specific flow path." This is a modification of Kurin's original proposed construction that brings it closer to Magnolia's, but properly reflects the plain and ordinary meaning of a "diverter."

The asserted claims require that the diverter have one incoming flow path and at least two outgoing flow paths, with the diverter functioning to direct the fluid flow to one of the outgoing flow paths. The relevant specifications, however, never use the term "diverter." Rather they ***always*** refer to a "diversion mechanism," and disclose two examples of such mechanisms. Thus, consistent with its plain and ordinary meaning and considered in light of the specification, the term "diverter" refers to a "mechanism" that "directs the fluid flow down a specific path."

Magnolia's proposed construction is ambiguous and inconsistent with the plain meaning of a "diverter." The plain and ordinary meaning of a "diverter" does not include inlets or outlets, rather a "diverter" is a mechanism placed in a structure that has inlets and outlets to control the flow of incoming fluid and direct it down a

particular selected path – such as to one of the outlets. Moreover, this is exactly how the diversion mechanisms are described in the specification. The "diversion mechanisms" disclosed in the asserted patents are the specific structures that control flow, diverting the fluid flowing from an inlet to one or the other of two possible outlets. Magnolia's proposed construction lacks the very core of the meaning of a diverter, instead defining only a forked or split path without any mechanism to perform the claimed function of controlling which outlet the fluid flows to.

Magnolia's reliance on expert testimony to try to overcome clear intrinsic evidence regarding this claim term is improper. *See Profectus Tech. LLC v. Huawei Techs. Co.*, 823 F.3d 1375, 1380 (Fed. Cir. 2016) (quoting *Phillips v. AWH Corp.*, 415 F.3d 1303, 1324 (Fed. Cir. 2005) ("Extrinsic evidence [*e.g.*, expert testimony] may not be used 'to contradict claim meaning that is unambiguous in light of the intrinsic evidence.'"). The intrinsic record is clear, and no expert or other extrinsic evidence is required to properly construe the term "diverter." Moreover, Dr. Santiago's testimony only confirms Kurin's construction, as Dr. Santiago defines a diverter to be a "diverter valve" – which when looked at as a complete, functioning device, includes a mechanism that directs fluid flow down a specific path. JA0177-181, JA0193-199 (Declaration of Warren Heim ("Heim Decl.") at ¶¶54-58, ¶¶83-95). Dr. Santiago's further

reference to certain highly specialized valves that do not have moving parts at the point of flow control are not relevant or appropriate. The valves cited by Dr. Santiago include those used in household plumbing, sewage management, oil pipelines, and automobile exhaust. JA0174-193 (Heim Decl. at ¶¶50-82). These uses are radically different from the blood draw context of the '001 and '689 in the fluid being managed, the size of the "pipes," the volume being managed, and a host of other considerations. *Id.* To the extent that this Court determines it is appropriate to consider extrinsic evidence, as explained by Mr. Heim, a person of ordinary skill in the art at the time of the alleged invention would have understood the term "diverter" as used in the claims to refer to a mechanism that directs fluid flow down a specific path. JA0171-174 (Heim Decl. at ¶¶42-49).

The term "diverter" in the asserted claims is properly considered a means-plus-function term because the claims lack sufficient structure to perform the claimed function of controlling fluid flow from the patient. The specifications disclose two structures for performing this function: (i) a switchable valve, or (ii) flow control blocks. To the extent this Court finds that "diverter" is not a means-plus-function limitation in any of the claims, it should be construed consistently with both its plain and ordinary meaning and the usage of "diversion mechanism" in the specification to mean "a mechanism that directs flow down a specific path."

3. Plaintiff's Reply Position

Kurin's Answering Brief reflects near total capitulation on "diverter." On the question of means-plus function, it chose not to say anything about the structural language in '001 claims 1, 21 and 28, focusing only on the language of claim 23 of the '689 Patent. In order to simplify the issues, Magnolia will drop '689 claim 23. As such, no disputed means-plus-function issues remain for "diverter."

Kurin also dropped a significant objectionable aspect of its backup (ordinary meaning) proposal—the requirement that the diverter be "movable." Assuming Kurin intends to stand by its concession (that a diverter need not be "movable"), the parties' proposed constructions are substantially aligned.

Means-Plus-Function for '001 Claims 1, 21, 28 – Kurin's Answering Brief Failed to Address This Issue: In its Answering Brief, Kurin fails to discuss why any of the '001 claims should be construed as means-plus-function.[14] *See* Kurin Answering Br. at 46-52 (not discussing '001 Patent claims 1, 21 and 28). Kurin only discussed claim 23 of the '689 Patent. *Id.* at 47-48.

[14] Kurin cannot cure this failure in its sur-reply either as "new arguments in reply briefs are prejudicial and unfair, because a party cannot respond." *Socket Mobile, Inc. v. Cognex Corp.*, No. 17-156, 2017 WL 3575582, at *5 (D. Del. Aug. 18, 2017).

Kurin's failure to address the '001 Patent claims is especially telling given that Magnolia cited to and discussed the key structural language in the '001 claims, showing how the claims themselves define the diverter as a component with an inlet and two outlet branches for directing fluid flow. Magnolia Opening Br. at 11. Given that Kurin bears the burden of proof on this issue, its failure to address the claims resolves the inquiry in Magnolia's favor.

Means-Plus Function for '001 Claims 1, 21, 28 – Even if Kurin Had Addressed This Issue, It Can Not Meet The Means-Plus-Function Burden:

The case law is clear that where, as here, a disputed claim term does not use the word "means," there is a presumption that means-plus-function *does not apply*. *Zeroclick, LLC v. Apple Inc.*, 891 F.3d 1003, 1007 (Fed. Cir. 2018). To overcome that presumption, Kurin needs to demonstrate that, from the perspective of a skilled artisan, "the claim term fails to recite sufficiently definite structure or else recites function without reciting sufficient structure for performing that function." *Id.* (citing *Williamson v. Citrix Online, LLC*, 792 F.3d 1339, 1348 (Fed. Cir. 2015)).

Kurin has made no such showing. Nor can it, as the asserted '001 Patent claims consistently and unequivocally describe the claimed diverter as a component with an *inlet* and *two outlet branches* for directing fluid flow. *See* '001 Patent, Claim 1 ("a diverter having an *inlet*, a *first outlet* in fluid communication

with the reservoir, and a *second outlet*"), Claim 21 ("the diverter including an *inlet*, an *outlet*, and *a reservoir configured to receive an initial volume* of bodily fluid"), Claim 28 ("The apparatus of claim 21, further comprising: a sample vessel fluidically coupleable to the *outlet of the diverter*"). And as Kurin's own expert concedes, a "diverter" can be "anything that diverts." JA0171 (Heim Decl.) ¶ 42.

Kurin argues that the claims describe the diverter in "primarily functional" language. Kurin Answering Br. at 47. Even if that were true (and it is not, as shown above), it would not end the inquiry. The Federal Circuit has explained, "the fact that a particular mechanism … is defined in functional terms is not sufficient to convert a claim element containing that term into a 'means for performing a specified function' within the meaning of section 112(6). Many devices take their names from the functions they perform." *Greenberg v. Ethicon Endo-Surgery, Inc.*, 91 F.3d 1580, 1583 (Fed. Cir. 1996). Rather, "[w]hat is important is not simply that [it] is defined in terms of what it does, but that the term, as the name for structure, has a reasonably well understood meaning in the art." *Id.*

Kurin's reliance on the *MTD* case is inapposite for multiple reasons. First, in *MTD*, there was *unrebutted* expert testimony that "'mechanical control assembly' does not bring to mind any specific structure to a person of ordinary skill in the art." *MTD Prods. Inc. v. Iancu*, 933 F.3d 1336, 1344 (Fed. Cir. 2019).

Here, both sides' experts *agree* that "diverter" is a device that diverts the flow of fluid. JA0171 (Heim Decl.) ¶ 42 ("Pursuant to the language of these claims, the 'diverter' causes diversion of fluid flow from the inlet to either the first outlet or the second outlet. The term 'diverter'… simply means anything that diverts"), JA0172 (Heim Decl.) ¶ 43 ("a person of ordinary skill in the art would understand the term 'diverter' used in the claims as being the thing that causes 'diversion' or 'diverting' to occur"); JA0042-43 (Santiago Decl.) ¶ 21 ("engineers use the term "diverter," … to refer to a class of devices or structures that facilitate diversion of fluid flow").

Second, in *MTD*, the term "mechanical control assembly" was identified as being "similar to other generic, black-box words" and "does not have an established meaning in the art and instead merely operates as a generic label for a collection of parts." *MTD*, 933 F.3d at 1343-44. In this case, the word "diverter" is self-explanatory: a structure that can divert something from an inlet to one of multiple outlets, not a generic black box. JA0171 (Heim Decl.) ¶ 42; JA0042-43 (Santiago Decl.) ¶ 21. Kurin's reliance on *Cross Med.* is even further misplaced, as the term at issue in that case was "securing *means*," which uses the triggering word "means" that creates the presumption means-plus function applies. *Cross Med. Prods., Inc. v. Medtronic Sofamor Danek, Inc.*, 424 F.3d 1293, 1307 (Fed. Cir. 2005).

Kurin's Backup (Ordinary Meaning) Construction: Kurin substantially changed its backup construction in its Answering Brief, dropping the requirement that the claimed diverter "can be moved" and adding a requirement that fluid flow must be directed "down a specific flow path." *Compare* D.I. 48-1 at 11 ("[M]echanism that can be moved to redirect fluid from one path to another path.") *with* Kurin Answering Br. at 47 ("[A] mechanism that directs fluid flow down a specific flow path.").

Apparently realizing that its originally proposed construction was a loser, Kurin dropped "can be moved." Taken at face value, the parties' current competing proposals would, therefore, seem not that far apart.

It appears, however, that Kurin may intend to use the word "mechanism" as a backdoor for later arguing to the jury that the diverter must include *moving parts*—the very limitation Kurin purports to have dropped from its construction. For example, Kurin's expert, Mr. Heim, argues repeatedly that "a person of ordinary skill in the art at time of the '001 and '689 Patents would have understood 'mechanism' as used in the Patents' specifications as having parts that move relative to each other." JA0172 (Heim Decl.) ¶ 44; *see also id.* JA0174 (Heim Decl.) ¶ 48 ("it has been a long-standing understanding that mechanisms have parts that move"); JA0174 (Heim Decl.)¶ 49 ("one of ordinary skill would understand that the claimed 'diverters' are diversion mechanisms and include moving parts.").

It is well-settled law that "the embodiments in the specification do not limit broader claim language." *Eolas Techs. Inc. v. Microsoft Corp.*, 399 F.3d 1325, 1336 (Fed. Cir. 2005). The patentee used the term "diverter," not "mechanism," indicating that the claim should not be so limited. "Absent such clear statements of scope, we are constrained to follow the language of the claims, rather than that of the written description." *Teleflex*, 299 F.3d at 1328.

Kurin's addition of "down a specific flow path" is also problematic. It not only improperly seeks to narrow the claims, but also injects unnecessary ambiguity. The claims themselves define where the fluid is being directed in the context of the particular claim. *See, e.g.*, '001 Patent, Claim 21 ("the diverter configured to divert the flow of bodily fluid to the second fluid flow path as a result of receiving the initial volume of bodily fluid from the patient and substantial pressure equalization"). The specification also clearly discloses diversion among multiple possible paths. *See, e.g.*, '689 Patent, 6:61-66, 7:34-44. Kurin appears to agree, as it acknowledges that the diverter "directs the fluid flow to one of the outgoing flow *paths*." Kurin Answering Br. at 42.

4. Defendant's Sur-Reply Position

Magnolia's assertion that Kurin failed to argue that claims 1, 21, and 28 of the '001 patent are means-plus-function is wrong. Kurin opens by stating that "All of the limitations in the asserted claims requiring a 'diverter' are properly

considered 'means-plus-function' claims." *Supra*, p. 45. As explained in detail, "diverter" is means-plus-function in the '001 patent because the claims recite insufficient structure for performing the claimed function of transitioning between first and second operating modes to: (a) direct fluid flow first from the inlet to the first outlet, then from the inlet to the second outlet (claim 1), or (b) divert flow from a first fluid flow path to a second fluid flow path (claim 21). *See Williamson v. Citrix Online, LLC*, 792 F.3d 1339, 1349 (Fed. Cir. 2015) (holding presumption can be overcome if claim recites function without sufficient structure); *MTD Prod. Inc. v. Iancu*, 933 F.3d 1336, 1343 (Fed. Cir. 2019) (holding "configured to" is functional language). The claimed structure is simply inlets, outlets, flow paths, and a reservoir, but defining paths is insufficient to *direct* or *divert flow* to one or the other path. Given the large number of asserted claims and limited briefing, Kurin used claim 23 of the '689 patent to explain this argument, but never limited its position to this claim.

Kurin's position is that expert testimony is unnecessary to resolve the claim construction issues. The Heim Declaration is submitted only in response to Magnolia's Santiago Declaration. Kurin requests consideration of the Heim Declaration only if the Santiago Declaration is considered. Expert testimony is not required to demonstrate a term is means-plus-function. *See Ultra-Mek, Inc. v. United Furniture Indus., Inc.*, No. 1:18CV281, 2019 WL 4723351, at *9

(M.D.N.C. Sept. 26, 2019) (citing *Personalized Media Commc'ns, LLC v. Int'l Trade Comm'n*, 161 F.3d 696, 704 (Fed. Cir. 1998)) (explaining that there is no requirement to "submit any extrinsic evidence or rely on any evidence other than the words of the claim itself.").

If the Court considers expert testimony, Mr. Heim confirms that "diverter" is a means-plus-function term because "[t]he term 'diverter' does not have a particular structural meaning in medical devices, but rather simply means anything that diverts." JA0171 (Heim Decl. at ¶ 42); *cf. MTD*, 933 F.3d at 1343-44 (holding expert testimony that a term "does not bring to mind any specific structure to a person of ordinary skill in the art" supported means-plus-function determination). Magnolia's partial quotation of this statement to make it appear that Mr. Heim agrees with Dr. Santiago is highly misleading. *See supra*, p. 54.

If "diverter" is not means-plus-function, "diverter" should be construed to mean "a mechanism that directs flow down a specific path". First, if "diverter" connotes enough structure to avoid means-plus-function treatment, this is the plain and ordinary meaning. As discussed *supra*, p. 48, the specification always uses the terms "divert" or "diversion" in connection with the term "diversion mechanism." ['001 patent, 2:39-54, 6:60-9:15, 9:34-48, Fig. 9]. "When a patent 'repeatedly and consistently' characterizes a claim term in a particular way, it is proper to construe the claim term in accordance with that characterization." *GPNE Corp. v. Apple*

Inc., 830 F.3d 1365, 1370 (Fed. Cir. 2016). Even the specification's broadest disclosure of this concept recites a "diversion mechanism", stating that "[m]any different types of diversion mechanisms can be used…." ['001 patent, 7:49-50].

One of skill would understand "diverter" to refer to the diversion mechanism and understand "diverter" to mean "a mechanism that directs flow down a specific path." *See* JA0172 (Heim Decl. at ¶ 43).

D. "Housing"

Term	Magnolia's Proposed Construction	Kurin's Proposed Construction
"housing" '483 Patent: claims 1, 9, 18, 24 '139 Patent: claims 1, 13, 19, 23, 27	Plain and ordinary meaning. If construction is necessary, "case or enclosure."	Original/Answering: "a casing that encloses one or more components" ('483 Patent, claims 1, 9, 18; '139 Patent, claims 1, 13, 19, 23, 27) Means-plus-function (*see* below) or, in the alternative, "a casing that encloses one or more components" ('483 Patent, claim 24) Function: The function of the "housing" is to transition from the first operating mode to the second operating mode. Structure:

		The structure of "housing" is disclosed in the '483 patent's specification at 8:33-15:34, 15:39-20:16 and in Figs. 2-5, 8-14, 16-18.

1. Plaintiff's Opening Position

"Housing" is a common term with an easily understood meaning used in the claims of the '483 and '139 patents. It commonly refers to the case or enclosure of a wide variety of objects, from consumer electronic products to medical devices.

'483 Claims 1, 9, 18 and '139 Claims 1, 13, 19, 23, 27: Based on its proposed construction of "housing" for these claims, Kurin agrees that a "housing" is a structure that has a plain and ordinary meaning to the skilled artisan.

The parties' competing constructions share some common ground. Both use the word "case" (or "casing") in their proposed construction. Where Kurin's proposal errs is in the ways it further limits the "casing." It wrongly and without support requires the casing to enclose "one or more components." A housing can enclose an empty space, both in common usage and in the usage of the claims of the patents—for example, the recited "first fluid flow path" and "second fluid flow path" ('483 Patent, Claim 9) or the recited "fluid reservoir" ('483 Patent, Claim 1) are all empty spaces.

'483 Claim 24: For this claim, Kurin proposes, contrary to black-letter patent law, that "housing" should be construed differently than in all the other

claims. *See Omega Engineering, Inc, v. Raytek Corp.*, 334 F.3d 1314, 1334 (Fed. Cir. 2003) ("[W]e presume, unless otherwise compelled, that the same claim term in the same patent or related patents carries the same construed meaning.").

Even if claim 24 was the only claim that used "housing," it would still be error to construe it as means-plus-function. A housing is a well-known structure (as Kurin admits); a term that recites structure, not functionality, is not a means-plus-function term. *Skky, Inc. v. MindGeek, s.a.r.l.*, 859 F.3d 1014, 1019-20 (Fed. Cir. 2017). Second, "housing" does not use the word "means," so the presumption against means-plus-function applies. Third, even if "housing" were not a known structure, claim 24 sets forth the specific structures of the "housing," making 112 ¶ 6 inapplicable. *Williamson*, 792 F.3d at 1348.

Finally, even if the Court were to consider means-plus-function, Kurin failed to provide a rational proposed structure for "housing," just as it failed to do for "diverter."[15] As just one example of many, Kurin cites to the '483 patent at 12:31-54, which discusses various features of the transfer device 200 without once mentioning the housing. "Structural features that do not actually perform the

[15] Kurin consistently fails to provide pinpoint citations to rational corresponding structures for its proposed means-plus-function terms: "diverter" (1.5 columns, 4 figures); "housing" (11.5 columns, 14 figures); "junction" (1.5 columns, 4 figures); "reservoir" (5.5 columns, 6 figures); "blood sequestration device" (8 columns, 7 figures); "bodily fluid sequestration device" (13 columns, 13 figures); "flow control mechanism (14 columns, 36 figures).

recited function do not constitute corresponding structure and thus do not serve as claim limitations." *Asyst*, 268 F.3d at 1370.

This Court has previously curbed a defendant's attempt to overload the corresponding structure with irrelevant material. *See Intel Corp. v. Broadcom Corp.*, 172 F. Supp. 2d 515, 536 (D. Del. 2001). By failing to provide a rational and reasonable proposal as to the claimed structure, Kurin invites legal error. *See Northrup Grumman Corp. v. Intel Corp.*, 325 F.3d 1346, 1352 (Fed. Cir. 2003) (reversing for including unwarranted additional elements in the structure because "[b]y including those additional elements, the court erred").

2. Defendant's Answering Position

The use of the term "housing" is an example of Magnolia's claiming tactics, which create confusion as Magnolia has attempted to expand the coverage of its patent claims well beyond the scope of its actual inventions. While typically the same terms are used to mean the same thing across a patent portfolio, here, Magnolia has used the term "housing" in a completely different way in claim 24 of the '483 patent as compared to elsewhere in its portfolio. For the other asserted claims, "housing" should be construed according to its plain and ordinary meaning as "a casing that encloses one or more components." *See* JA0349 (Oxford Dictionary of English, 3rd Ed. (2010)) (defining "housing" as "a rigid casing that encloses and protects a piece of moving or delicate equipment"). Claim 24 of the

'483 patent, however, uses functional language, requiring that the "housing" must be "configured to" transition from the first operating mode to the second operating mode, thereby redirecting fluid flow. *See MTD Prod.*, 933 F.3d at 1343.

First, with respect to all but claim 24 of the '483 patent, the plain and ordinary meaning of "housing" is "a casing that encloses one or more components." *See* JA0349 (Oxford Dictionary of English, 3rd Ed. (2010)). "Housing" is not necessarily a term that all jurors may be familiar with, particularly as used in the context of a medical device, so such an explanatory construction is appropriate. It is also completely consistent with the way the term "housing" is used in the asserted patents, which use the term to describe the outer case of the device that encloses the working parts. [*See*, *e.g.*, '483 patent, 4:19-31 and Fig. 1 (explaining that "housing 101 can house at least a portion of the fluid control mechanism 130 and first reservoir 180")].

In an effort to avoid problems proving infringement, and citing nothing, Magnolia seeks to broaden the meaning of "housing" to encompass any "case or enclosure." There is no basis for this proposed construction, which empties the term "housing" of any real meaning. The very term "housing" reflects the fact that the case or enclosure "houses" something, such as "moving or delicate equipment," not just empty space. *See* JA0349 (Oxford Dictionary of English, 3rd Ed. (2010)). Moreover, this is exactly how the term is used in the asserted patents, wherein the

housing always "houses" at least some other components of the device. [*See, e.g.*, '483 patent, 10:14-19 and Figs. 3, 7 (showing components of the "flow control mechanism 230," such as the "first plunger 255," as within "housing 201"); '483 patent, 16:10-15 and Figs. 14, 16 (showing components of the "flow control mechanism 330," such as the "first plunger 355" as within "housing 301"); '139 patent, 6:9-11, 6:49-53, 24:13-15, and Figs 31-32 (showing "flow control mechanism 740" within "housing 701")].

Claim 24 of the '483 patent, however, presents a different usage of the same term, and requires a different construction. *See Haemonetics Corp. v. Baxter Healthcare Corp.*, 607 F.3d 776, 782 (Fed. Cir. 2010) (holding that the intrinsic evidence requires a different construction for the same term as used "in the context of different claims"). Claim 24 uses functional language requiring a "housing" that is "configured to" transition from the first operating mode to the second operating mode, thereby redirecting fluid flow. *See MTD Prod.*, 933 F.3d at 1343. Although the claim recites some structure for the "housing" – an "inlet port," an "outlet port," and a "vent" – as with the functional "diverter" claims discussed above, this structure is not sufficient to perform the claimed function of redirecting flow. *See Cross Med. Prod.*, 424 F.3d at 1307–08. Thus, unlike the other asserted claims, in claim 24 the term "housing" is a means-plus-function limitation.

As discussed above, the structures disclosed in the asserted patents for performing the claimed function of directing flow are: (i) a switchable valve, or (ii) flow control blocks. ['001 patent, 7:50-9:15; '689 patent, 7:51-9:15]. No other structures for performing the claimed function are disclosed.

3. Plaintiff's Reply Position

'483 Claims 1, 9, 18 and '139 Claims 1, 13, 19, 23, 27: For these claims, the parties are largely in agreement on the proper construction. Kurin agrees that plain and ordinary meaning applies. Kurin Answering Br. at 58. It also agrees a housing is a "casing." *Id.* at. 57. Where it disagrees, is with respect to the additional restriction it seeks to impose, i.e., that the claimed housing "encloses one or more components." *Id.*

In making its argument, Kurin again loses sight of the fact that the claims must be construed from the perspective of the skilled artisan. *Searfoss*, 374 F.3d at 1149. And the proper construction from the skilled artisan's perspective starts with the actual claim language and the teachings of the specification. *Phillips v. AWH Corp.*, 415 F.3d 1303, 1313 (Fed. Cir. 2005).

The claims at issue affirmatively recite what the claimed housing encloses. Sometimes it encloses structural components. For example:

- "seal member" and "vent" ('483 Patent, Claim 1)
- "vent" ('483 Patent, Claims 9, 18)

- "flow control mechanism" and "valve" ('139 Patent, Claims 1, 13, 23)

Sometimes it encloses fluid storage or transit spaces, both of which will sometimes be empty and will sometimes have fluid. For example:

- "fluid reservoir" ('483 Patent, Claim 1)
- "first fluid flow path" and "second fluid flow path" ('483 Patent, Claim 9)
- "internal fluid reservoir" ('139 Patent, Claims 1, 13, 23)

The specifications of both patents also teach a housing that encloses an empty space. In the '483 Patent, Figure 5 teaches a housing 201 that encases inner volume 207 (i.e., empty space). The inner space *is capable of* receiving a portion of the flow control mechanism 230, but the point is that the '483 Patent calls 201 a housing regardless of whether the flow control mechanism is occupying the empty space or not. '483 Patent, 8:54-57 ("The proximal end portion 202 of the housing 201 is substantially open such that the inner volume 207 can receive at least a portion of the flow control mechanism 230 (see e.g., FIG. 3)."); *see also* '139 Patent, 6:9-12 ("As shown in FIG. 1, the housing 101 defines an inner volume 111 that can movably receive and/or movably house at least a portion of the flow control mechanism 140, as described in further detail herein.").

Given that the claims and both specifications either (1) specifically recite what the claimed housing does and does not enclose or (2) recite a housing that

encloses empty space, it would be clear error (not to mention confusing for the jury), to include Kurin's proposed requirement of "encloses one or more components."[16]

'483 Claim 24: Kurin's means-plus-function argument for claim 24 of the '483 Patent should be rejected out of hand given Kurin's failure to provide any reasonable proposal as to the claimed structure. For the first time in its Answering Brief, it proposes a pair of structures, "(i) a switchable valve, or (ii) flow control blocks" found in *other* Magnolia patents: the '001 and '689 Patents. *See* Kurin Answering Br. at 59 (citing as support, "['001 patent, 7:50-9:15; '689 patent, 7:51-9:15]"). Kurin fails to discuss or cite *any* structure from the '483 Patent in which the alleged means-plus-function term is found (despite having cited 11.5 columns and 14 figures from this patent in the Joint Claim Construction Statement). *See DE Techs., Inc. v. Dell, Inc.*, 428 F. Supp. 2d 512, 518 (W.D. Va. 2006) (stating that "[a] corresponding structure must be disclosed in the specification" and that corresponding structure cannot be provided "outside of the specification" (citing *Harris Corp. v. Ericsson Inc.*, 417 F.3d 1241, 1253 (Fed. Cir. 2005)).

[16] Kurin hopes to create a non-infringement argument by (wrongly) rewriting the claims to require any "housing" to enclose "*components*." Then it will argue its Kurin Lock device does not have a housing that "encloses one or more *components*."

Kurin's construction should be rejected for the additional reason that Kurin has failed to overcome the presumption against means-plus-function that arises from the lack of the word "means." Kurin needed to offer *evidence* (not just attorney argument) regarding whether there is sufficiently definite structure as understood from the perspective of the skilled artisan. *Zeroclick*, 891 F.3d at 1007. Kurin's expert, Mr. Heim, offers nothing.

Nor could Kurin's expert offer such testimony, given that Kurin admits that the claims recite structures such as an "inlet port," an "outlet port," and a "vent." Kurin Answering Br. at 59. The inlet and outlet ports are both fluid flow paths. '483 Patent, Claim 24 at 22:39-40. The vent "allow[s] air to exit the housing as blood enters the first fluid flow path." *Id.*, 22:47-48.

Not only does the claim recite structure, it recites the structures necessary to allow the housing to operate in the two modes alleged by Kurin to be functional. *See Wasica Finance GmbH v. Schrader Int'l, Inc.*, No. , 2019 WL 1011321, at *8 (D. Del. Mar. 4, 2019) (concluding that a "switching device" that switched a receiver from normal mode to pairing mode was sufficiently definite because it was defined in technical dictionaries even though not explicitly defined in specification).

4. Defendant's Sur-Reply Position

Kurin's construction of "housing" should be adopted for all but claim 24 of the '483 patent so the jury understands that "housing" means a casing that encloses one or more components. This is consistent with the term's plain meaning and use in the asserted patents, where the housing always encloses at least one component. That the claimed housing has "ports" reinforces that these components involved in fluid flow are internal to the housing. For example, each independent claim of the '139 patent recites a "flow control mechanism" and "valve" "disposed in" the housing. ['139 patent, claims 1, 13, 23].

In all three embodiments disclosing a valve, the valve is enclosed within the housing. ['139 patent, 7:3-20 and Figs. 1-2 (flow control mechanism 140, with valve within housing 101; lumens for fluid communication and therefore valve to control "flow of a fluid" are within the housing); 20:35-63 and Figs. 28-30 (valve 639 enclosed within housing 601); 25:3-53 and Figs. 33-34 (in Fig. 33, valve (not shown) in first lumen 746 is within housing 701)]. In the other embodiments, components that define lumens and/or direct fluid flow are within the housing during operation. ['139 patent, 9:27-10:8 and Fig. 3 (flow control mechanism 240 defines lumens within the housing 201); 10:50-53, 11:38-12:67 and Figs. 6-8 (flow control mechanism 340 within distal end portion 303 of housing 301); 14:15-17, 14:50-15:61 and Figs. 13-14 (flow control mechanism 440 within housing 401);

19:37-41 and Fig. 22 (members 540 and 541 of flow control mechanism 540 "disposed within" housing 501); 27:4-26 and Figs. 36-37 (flow control mechanism 840 defining lumens 846 and 847 "disposed within" housing 801)].

Claim 1 of the '483 patent discloses a "seal member" that is part of the fluid reservoir "disposed in" the housing and claim 18 discloses a "seal" that is part of the reservoir "at least partially defined by" the housing. In both embodiments featuring seals, the seals are enclosed within the housing. ['483 patent, 10:63-12:30 and Figs. 7-9 (*e.g.*, 12:18-22, "the first reservoir 280 is formed by a portion of the inner volume 207 of the housing 201 … between the first plunger 255 (*e.g.*, the seal element 257) and the second plunger 260 (*e.g.*, the second and third seal elements 265 and 266)."); 16:10-15; 17:1-63 and Figs. 14, 16-18 (seal element 357 is part of first plunger 355; seal member 363 is part of second plunger 360; both plungers are part of flow control mechanism 330 "disposed within" housing 301)].

Claim 9 of the '483 patent discloses "first" and "second" "fluid flow path[s]" "disposed in" the housing. In all embodiments, these flow paths are defined by portions of the "flow control mechanism" enclosed within the housing. ['483 patent, 5:39-43 and Fig. 1 ("The flow control mechanism 130 … disposed within the housing 101 … defines, at least partially, a first fluid flow path 181 and a second fluid flow path 191."); 10:14-19, 12:15-30, 13:41-50, 14:54-15:16 and Figs. 10-11 (arrows CC and EE indicate first and second fluid flow paths within

housing 201; paths are bounded by first plunger 255 and second plunger 260 of flow control mechanism 230); 16:10-15, 18:55-64, 19:46-20:4 and Figs. 17-18 (arrows GG and II indicate first and second fluid flow paths within housing 301; paths are bounded by first plunger 355 and second plunger 360 of flow control mechanism 330)]. Thus, the claimed flow paths are not simply empty space. Moreover, Magnolia's argument that the housing is a housing even when empty is immaterial in view of what the claims require—*i.e.*, components "disposed in" the housing.

Turning to the means-plus-function "housing" of claim 24 of the '483 patent, this claim recites insufficient structure to perform the claimed function; simply defining ports and flow paths is insufficient to accomplish the claimed transition between modes that redirects fluid flow. In its Answering Brief, Kurin inadvertently provided the wrong citation for the structure of the "housing." *Supra*, p. 65. The correct citation, narrowed from Kurin's disclosure in the Joint Claim Construction Chart, is: the housing is "housing 201" or "housing 301," which must interact with other components as described at '483 patent, 8:33-9:12, 9:26-12:30, 12:55-15:6, 15:26-34 or 15:42-17:32, 17:51-67, 18:9-20:4, in order to perform the claimed function.

E. "Junction"

Term	Magnolia's Proposed Construction	Kurin's Proposed Construction
"junction" '689 Patent: claims 1, 8, 17	Plain and ordinary meaning. If construction is necessary, "place at which two or more things are joined."	Original: Means-plus-function Function: The function of the "junction" is to direct fluid flow to one path or to a different path. Structure: The structure of the "junction" is disclosed in the '689 patent's specification at 7:50-9:15 and in Figs. 6A, 6B, 7A, 7B. In the alternative, if not held to be a means-plus-function term, "junction" should be construed to mean "mechanism that can be moved to redirect fluid from one path to another path." Answering: Means-plus-function or "a mechanism that directs flow down a specific path."

1. Plaintiff's Opening Position

"Junction" is another common term with an easily understood meaning. It requires no construction beyond its plain and ordinary meaning. A junction is a place where two or more things are joined—just as the term is used throughout the '689 patent.

In Claim 23 of the '689 patent, for example, the claimed junction is within the diverter and "includ[es] an inlet fluidically coupled to the input tube, a first outlet fluidically coupled to the reservoir, and a second outlet fluidically coupled to an output tube." The junction also "allow[s] an initial volume of biological fluid to flow…towards the first outlet," and "transitions…to allow a subsequent volume of biological fluid…to flow to the output tube via the second outlet. '689 Patent, Claim 23. In short, the claimed junction is an intersection of two or more flow paths—consistent with the term's plain and ordinary meaning.

"Junction" only appears once in the '689 specification, and in that instance it is used consistently with its plain meaning. The specification explains, in the context of the "many different types of diversion mechanisms that can be used to divert the flow of bodily fluids from a patient," that "one embodiment of the diversion mechanism 512…includes a switchable valve 602 that pivots about a pivot point 604 positioned at the *junction* of the first sterile output tubing 516 and the second sterile output tubing 518." *Id.*, 7:50-55 (emphasis added). This

example junction is illustrated in Figures 6A and 6B (with annotations added), below:

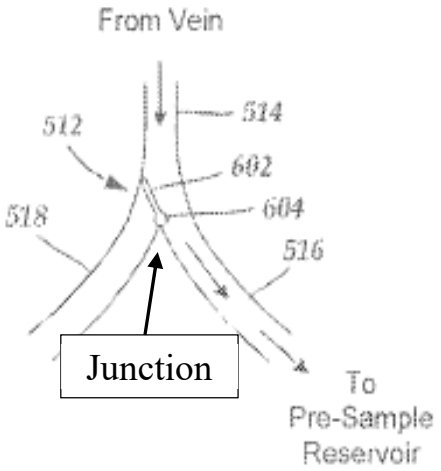


Fig. 6A

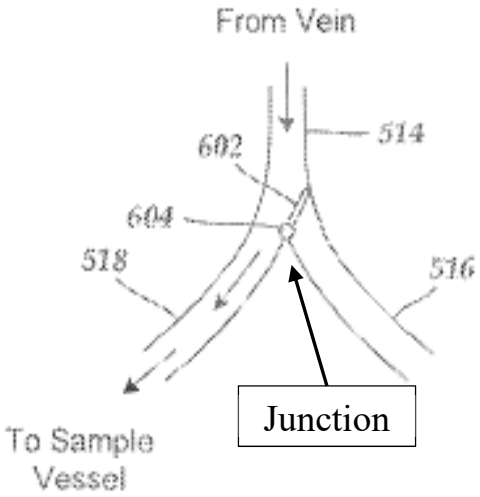


Fig. 6B

While the patent describes a "switchable valve 602" at the junction, nothing in the patent suggests the term "junction" itself carries anything other than its ordinary meaning. Indeed, the specification distinguishes between the "switchable valve 602," which does move, and the "junction of the first sterile output tubing 516 and the second sterile output tubing 518," which does not. *Id.*, 7:50-55, Figs. 6A, 6B.

Kurin's backup construction, requiring that the claimed junction be a mechanism that "can be moved" to redirect fluid from one path to another, is misguided. It would not only improperly read into the claims a limitation from a preferred embodiment, in violation of *Phillips*, it reads in an aspect that—according to the specification—relates to a *different* component of that preferred

embodiment, *i.e.*, a "switchable *valve*" that "pivots about a pivot point." '689 Patent, 7:52-54. Further highlighting the futility of Kurin's argument—and the lengths Kurin will stretch to try to narrow the asserted claims—Kurin's proposed construction of "junction" is identical to its construction for "diverter," even though both terms appear in the same claim, and even though that claim unambiguously states that the "diverter includ[es] a…junction." *Id.*, Claim 23.

Kurin's argument that "junction" is a means-plus-function limitation also fails. A "junction" is structure, not function. *Skky*, 859 F.3d at 1019-20. And even if it were not sufficiently structural, the claims themselves define the junction as having finite structures. *See, e.g.*, '689 Patent, Claims 23 (junction including an inlet fluidically coupled to an input tube, a first outlet fluidically coupled to a reservoir, and a second outlet fluidically coupled to an output tube), 1, 24 (junction having an inlet and two outlets).[17]

2. Defendant's Answering Position

Magnolia's use of the term "junction" in the independent claims of the '689 Patent is another example of the challenge posed by Magnolia's prosecution strategy. The term "junction" appears just once in the '689 Patent specification, where it is used to describe the position of the "pivot point 604" for the

[17] Finally, Kurin again offers an overbroad citation to 1.5 columns and 4 figures of alleged structure.

"switchable valve" embodiment of the "diversion mechanism" shown in Figures 6A and 6B. ['689 patent, 7:51-55]. This "pivot point" is "positioned at the junction of the first sterile output tubing 516 and the second sterile output tubing 518." [*Id.*] Thus, in the specification the term junction is used to describe a location where two output tubes meet.

The specification does not ascribe ***any*** functionality to the "junction," it is simply a location. As explained in the specification, the function of directing flow down one or the other of the two "output tubings" that meet at the junction is performed by the "diversion mechanism" – the "switchable valve" that is positioned at the junction. ['689 patent, 7:51-8:7]. This all makes sense. The claims, however, require the junction to perform the functions that are ascribed to the "diversion mechanisms" in the specification.

Specifically, the claims require a "junction" that is "operable to" or "configured to" transition between a first state, wherein it directs fluid flow to one output tube, and a second state wherein it directs fluid flow down the other output tube. Adding to the confusion, in claims 1, 8, and 23 the "junction" alone must perform this function, while in claim 17 the "contaminant reservoir and the junction" must perform this function. Magnolia's use of the term "junction" in these claims is completely inconsistent with both the plain and ordinary meaning of the term and its usage in the specification.

Rather than using "junction" in its ordinary meaning, Magnolia has swapped the word "junction" for the term "diverter" as that term is used in the claims of the '001 patent, requiring it to perform the same function of directing flow down a specific path. Moreover, as with "diverter" in the '001 patent, although some of the claims recite some structure for the "junction" – *i.e.*, an "inlet" an "outlet[s]" – this structure is not sufficient to perform the claimed function. *See Cross Med. Prod.*, 424 F.3d at 1307–08.

Magnolia attacks Kurin for proposing the same construction for the terms "junction" and "diverter," yet the two terms are used to perform the same function in certain claims. While somewhat unusual, the fact that claim 23 of the '689 patent uses both terms "diverter" and "junction" does not alter the analysis. *See Bancorp Servs., L.L.C. v. Hartford Life Ins. Co.*, 359 F.3d 1367, 1373 (Fed. Cir. 2004) ("[I]t is not unknown for different words to be used to express similar concepts, even though it may be poor drafting practice."). Claim 23 of the '689 Patent requires a "diverter including a reservoir and a junction configured to control fluid flow from the patient," but it is the junction that must have the inlet and two outlets, and which must perform the function of directing the fluid flow to one or the other of the outlets. In the claims of the '001 patent, the "diverter" performs this function, but this is not inconsistent because claim 23 requires that the junction must be part of the diverter. Thus, claim 23 is simply narrower, in that

it specifically requires that the junction portion of the "diverter" must perform this function.

3. Plaintiff's Reply Position

Once again, Kurin fails to address the presumption that arises given the absence of the word "means." *Zeroclick*, 891 F.3d at 1007. Neither Kurin nor Kurin's expert, Mr. Heim, offers any testimony or evidence on this issue. That alone ends the inquiry. *Id.* at 1008 ("The court thus legally erred by not giving effect to the unrebutted presumption against the application of § 112, ¶ 6.").

Indeed, Kurin's Answering Brief *admits* that "the claims recite some structure for the 'junction' – *i.e.*, an 'inlet' an 'outlet[s].'" Kurin Answering Br. at 72. Kurin's expert, Mr. Heim, admits the same thing—specifically, that the junction includes "[a]n inlet, [t]wo destinations for the fluid entering the diverter through the inlet . . ., [a] first fluid flow path that has fluid flow from the inlet to the first outlet . . ., [a] second fluid flow path that has fluid flow from the inlet to the second outlet . . . ." JA0216 (Heim Decl.) App. B ¶ 4. Nothing more is required to sufficiently define the structure of the junction. *See LG Elecs., Inc. v. Bizcom Elecs., Inc.*, 43 F.3d 1364, 1372 (Fed. Cir. 2006) (finding "control unit" sufficiently defined by "a CPU and a partitioned memory system" for performing the functionality of "controlling the communication unit"), *overruled on other grounds, Quanta Computer, Inc. v. LG Elecs., Inc.*, 553 U.S. 617 (2008).

Further, "junction" is defined in the specification as a *noun* denoting structure as the structure created by paths being joined together—"the junction of the first sterile output tubing 516 and the second sterile output tubing 518," '689 Patent, 7:54-55. Kurin acknowledges this teaching. Kurin Answering Br. at 71. Its admission guts its argument. *See Wasica*, 2019 WL 1011321, at *8 (explaining that terms defined as nouns denoting structure in the specification or dictionary weighs against overcoming the presumption that § 112, ¶ 6 does not apply).

As discussed for "diverter," Kurin substantially changed its backup (ordinary meaning) construction, dropping the requirements that the claimed junction "can be moved" or needs to "redirect" the flow of fluid. *Compare* D.I. 48-1 at 17-18 ("[M]echanism that can be moved to redirect fluid from one path to another path.") *with* Kurin Proposed Construction at 74 ("[A] mechanism that directs fluid flow down a specific flow path."). However, that change does not address the more fundamental problem with Kurin's proposal, that its proposed ordinary meaning construction is simply not consistent with the ordinary meaning of "junction."

4. Defendant's Sur-Reply Position

"Junction" is a means-plus-function term because the recited structure is insufficient to perform the claimed function of transitioning between states to redirect fluid flow, as discussed s*upra*, pp. 76-77. *See Williamson,* 792 F.3d at

1349; *MTD*, 933 F.3d at 1343. Magnolia's characterization of the plain meaning of "junction" – "an intersection of two or more flow paths," *supra*, p. 73 – demonstrates this. An intersection *alone* is inherently not capable of directing fluid flow down one or the other path. Something more is required. Here, it is the mechanisms including a switchable valve or flow control blocks that perform this function in the specification of the '689 patent at 7:51-9:15.

If "junction" is not means-plus-function, Kurin's ordinary meaning construction should be adopted. As discussed *supra*, pp. 76-77, the claims require the junction to perform functions ascribed in the specification to the "diversion mechanism." Thus, for the same reasons discussed *supra* pp. 48-50, 58-59 with regard to "diverter," "junction" should be construed as "a mechanism that directs flow down a specific path." *See GPNE*, 830 F.3d at 1370.

F. "Reservoir"/"Contaminant Reservoir"

Term	Magnolia's Proposed Construction	Kurin's Proposed Construction
"reservoir" or "contaminant reservoir" '689 Patent: claims 8, 17 '483 Patent: claim 18	Plain and ordinary meaning. If construction is necessary, "receptacle designed to hold fluid."	Original/Answering: Means-plus-function term for claim 18 of the '483 patent and claims 8 and 17 of the '689 patent <u>Function</u>: For claim 18 of the '483 patent and claim 17 of the '689 patent, the function of the "reservoir" or "contaminant reservoir" is

		to transition from the first state to the second state. For claim 8 of the '689 patent, the function of "contaminant reservoir" is to direct a first portion of biological fluid. Structure: The structure of the "reservoir" is disclosed in the '483 patent's specification at 4:52-68, 8:33-36, 12:15-15:38, 15:39-47, 17:51-20:17, and depicted in Figs. 8, 10-11, 16-18. The structure of the "contaminant reservoir" is disclosed in the '689 patent's specification at 3:48-58; 4:31-49; 7:13-26; 7:50-9:15 and in Figs. 5, 6A, 6B, 7A, 7B.

1. Plaintiff's Opening Position

The word "reservoir" appears in all four asserted patents. For 10 of the 13 asserted independent claims that include this term ('001 Patent, Claims 1 and 21; '689 Patent, Claims 1 and 21; '483 Patent, Claims 1, 9 and 24; '139 Patent, Claims 1, 13 and 23), Kurin agrees no construction is necessary.

Yet for the other three asserted independent claims ('689 Patent, Claims 8, 17; '483 Patent, Claim 18), Kurin argues the term "reservoir" is subject to a

means-plus-function construction. This alone highlights the weakness of Kurin's proposed constructions. *See Omega Engineering*, 334 F.3d at 1334.

Moreover, in every claim in which it appears, the term "reservoir" is used consistently with its plain and ordinary meaning—*i.e.*, a receptacle designed to hold fluid. Claim 1 of the '689 patent, for example, which Kurin agrees needs not be construed, requires "a contaminant *reservoir* fluidically coupled to the first outlet of the junction; and… the junction operable to allow an initial volume of biological fluid to flow from the patient to the contaminant *reservoir*." *See also* '483 Patent, Claim 1 ("a fluid *reservoir* disposed in the housing and at least partially defined by a seal member, the fluid *reservoir* configured to receive an initial volume of blood withdrawn from the patient"); '001 Patent, Claim 1; '139 Patent, Claim 1; and the others.

Yet for Claim 8 of the '689 patent ("the contaminant *reservoir* and the junction being configured to direct a first portion of biological fluid into the contaminant *reservoir*"), Claim 17 of the '689 patent ("a contaminant *reservoir* fluidically coupled to the input tube and the output tube; and… the contaminant *reservoir* and the junction operable in a first state to allow a first portion of biological fluid to flow into the contaminant *reservoir*"), and Claim 18 of the '483 patent ("a *reservoir* at least partially defined by the housing, the *reservoir*

configured to receive an initial volume of blood withdrawn from the patient"), Kurin contends means-plus-function applies.

Kurin's position strains credulity. As Kurin concedes by not seeking construction of this same term in the majority of the asserted claims, "reservoir" is a quintessentially structural term and therefore not subject to means-plus-function construction. *Skky*, 859 F.3d at 1019-20. "Reservoir" has a well-known structural meaning—namely, a "receptacle designed to hold fluid," which Kurin does not contest. And "reservoir" is used consistently throughout the asserted claims, as shown above.

Finally, as with the previous terms where Kurin proposes means-plus-function, Kurin fails to provide a rational structure for "reservoir." As just one example of many, Kurin cites to the '483 patent at 12:66-13:21, which discusses movement of the actuator 270 without once mentioning a reservoir. This is legal error. *Northrup*, 325 F.3d at 1352.

2. Defendant's Answering Position

Magnolia's prosecution strategy has also caused problems with respect to the term "reservoir"/"contaminant reservoir." Like the term "housing," in many of the asserted claims the term "reservoir" is used in accordance with its plain and ordinary meaning, and to the extent it is required to perform any function, such function is consistent with the term's plain and ordinary meaning. For example,

claim 1 of the '483 patent requires a "fluid reservoir" that is "configured to receive an initial volume of blood withdrawn from the patient." ['483 patent, 20:52-55]. Kurin agrees that the term "reservoir" does not require construction and should be given its plain and ordinary meaning with respect to all such claims.

However, claims 8 and 17 of the '689 patent and claim 18 of the '483 patent ascribe specific functions to the "reservoir" and do not use the term consistent with its plain and ordinary meaning. Like the use of "housing" discussed above, these claims require a reservoir that is "configured to" ('689 patent, claim 8; '483 patent, claim 18) or "operable … to" ('689 patent, claim 17) direct the flow of fluid along a particular path and in two (2) of the claims to transition between two states in which the fluid flow is directed along different paths. For example, claim 18 of the '483 patent requires a reservoir that is:

> configured to transition from a first state such that the initial volume of blood flows from the inlet port toward a seal defining a portion of the reservoir, to a second state such that a subsequent volume of blood can flow from the inlet port toward the outlet port, thereby bypassing the reservoir and the initial volume of blood sequestered therein.

This is purely functional language and it is not consistent with the plain and ordinary meaning of the term reservoir. *See MTD Prod.*, 933 F.3d at 1343.

As with the functional "housing" claims discussed above, these three (3) claims recite no relevant structure for the "reservoir" and thus these must be considered means-plus-function limitations. *See Cross Med. Prod.*, 424 F.3d at

1307–08; *Haemonetics*, 607 F.3d at 782. Looking at the specific required functions to determine their corresponding structures, claims 8 and 17 of the '689 patent require the reservoir to perform the same functions as the two disclosed "diversion mechanisms:" (i) a switchable valve, or (ii) flow control blocks. ['689 patent, 7:51-9:15]. Likewise, claim 18 of the '483 patent requires the reservoir to perform the function of transitioning between the claimed first and a second state using the corresponding structure of the reservoir in the embodiments recited in the specification for making this transition. ['483 patent, 12:15-15:16 (describing the "first reservoir 280" and its interaction with other components in transitioning between states) and 17:51-20:4 (describing the "first reservoir 380" and its interaction with other components in transitioning between states).]

Thus, with respect to all but claim 18 of the '483 patent and claims 8 and 17 of the '689 patent, the term reservoir should be given its plain and ordinary meaning. With respect to these three (3) independent claims, however, the term is functionally claimed and should be construed as a means plus function limitation.

3. Plaintiff's Reply Position

Kurin's Answering Brief begins by making significant concessions. It agrees that, for 10 of the 13 claims, "'reservoir' does not require construction and should be given its plain and ordinary meaning." Kurin Answering Br. at 86. Kurin also admits that in some claims, "to the extent [the reservoir] is required to

perform any function, such function is consistent with the term's plain and ordinary meaning." *Id.* In other words, Kurin admits that the presence of some functional language may be consistent with an ordinary meaning construction.

Nonetheless, Kurin argues that in three claims, the use of "reservoir" is so materially different from the other 10 claims, that it warrants special treatment as a means-plus-function term. Kurin Answering Br. at 86.

Once again, Kurin fails to address in any meaningful way – much less overcome – the presumption against applying § 112, ¶ 6 that arises given the lack of the triggering word "means." *Zeroclick*, 891 F.3d at 1007. Kurin's expert, Mr. Heim, did not offer any testimony or evidence in support of Kurin's position that a skilled artisan would understand the terms to lack sufficient structure for performing the functionality. *Id.* Kurin's failure to offer evidence on this issue is fatal to Kurin's argument. *Id.*

Kurin also takes a cavalier approach to identifying the proper structures. Kurin originally identified six columns of text and five figures for the '483 Patent structure and two columns and five figures for the '689 Patent. D.I. 48-1 at 21-22. In its Answering Brief, it drops significant portions of its original proposal for both patents, but it never explains why nor does it confirm it is abandoning much of its original proposal. *Compare* D.I. 48-1 at 21-22 (defining several pages of structure) *with* Kurin Answering Br. at 87-88 ("(i) a switchable valve, or (ii) flow control

blocks"). Magnolia should not be forced to guess as to Kurin's constantly moving "structure" target. *See Finnigan Corp. v. Int'l Trade Comm'n*, 180 F.3d 1354, 1363 (Fed. Cir. 1999) ("A party's argument should not be a moving target.").

'689 Claim 8: Claim 8 recites that the contaminant reservoir is "fluidically coupled to the inlet port via a junction." '689 Patent, Claim 8 at 11:51-53. The claim goes on to recite "the contaminant reservoir and the junction being configured to direct a first portion of the biological fluid into the contaminant reservoir." *Id.*, 11:54-56. Thus, the claim itself recites that there is an opening (the inlet port) for fluid to enter the reservoir. Nothing more is needed.

Kurin's focus on the "configured to" language is also misplaced. The term Kurin is seeking construction on is "reservoir," not the broader phrase "the contaminant reservoir and the junction being configured to . . . ." A POSITA would readily understand that a reservoir is simply a receptacle designed to hold fluid. '689 Patent, 9:38-42.

'689 Claim 17; '483 Claim 18: Claim 17 recites "a contaminant reservoir fluidically coupled to the input tube and the output tube." '689 Patent, Claim 17, 12:32-33. Claim 18 recites similar structures. '483 Patent, Claim 18, 22:4-7. The claims further recite structures for performing a transition, which results in the bodily fluid that was initially flowing into the contaminant reservoir to subsequently flow into an output tube that directs the fluid to a sample reservoir.

'689 Patent, Claim 17, 12:37-48; '483 Patent, Claim 18, 22:13-18. Kurin relies upon nothing more than lawyer argument to support its view that the claims do not cite sufficient structure to perform the transition. Kurin is wrong.

The skilled artisan would appreciate that the claim language provides sufficient structure for performing Kurin's alleged functionality. Taking claim '689 claim 17 as an example, the "contaminant reservoir fluidically coupled to the input tube and the output tube." '689 Patent, Claim 17, 12:32-33. The contaminant reservoir "allow[s] a first portion of biological fluid to flow into the contaminant reservoir." *Id.*, 12:38-39. Then, the contaminant reservoir "sequester[s] the first portion of biological fluid in the contaminant reservoir, and … allow[s] a second portion of biological fluid to bypass the contaminant reservoir and to flow to the output tube." *Id.*, 12:41-44.

4. Defendant's Sur-Reply Position

One of skill may generally understand what a "reservoir" is, but, as discussed *supra*, p. 84, claims 8 and 17 of the '689 patent and claim 18 of the '483 patent ascribe functions to the reservoir that go far beyond a "receptacle designed to hold fluid," and lack sufficient structure for performing those functions. *See Williamson,* 792 F.3d at 1349. No expert testimony is required, and it is appropriate to consider the "configured to" language in making this assessment.

See MTD, 933 F.3d at 1342 ("In assessing whether the claim limitation is in means-plus-function format, we … look to the entire passage ….").

Claim 8 of the '689 patent recites "the contaminant reservoir and the junction being configured to direct" fluid into the reservoir. ['689 patent, 11:54-56]. One of skill might understand that a reservoir can "hold" or "receive" fluid, but claim 8 does not recite structure necessary to allow a reservoir to "*direct*" fluid flow. In the recited junction, simply defining paths and ports does not "direct" flow; something more is required. To be clear, the claimed reservoir corresponds to "pre-sample reservoir 504" (*see, e.g.*, '689 patent, 7:13-26 and Fig. 5), but the mechanisms disclosed at 7:51-9:15 are needed to perform the claimed function.

In Claim 17 of the '689 patent and claim 18 of the '483 patent, the contaminant reservoir (with the junction, for '689 claim 17) or reservoir (for '483 claim 18) is "operable … to" or "configured to" transition between two states in which fluid flow is directed along different paths. These claims provide some structure (*e.g.*, tubing) that links up flow paths. But nothing in the claims teaches how a reservoir can transition between states to direct fluid first along one path, then along another. The structures recited in the specifications are required to enable such an unusual reservoir to accomplish this. *I.e.*, in the '689 patent, the reservoir corresponds to "pre-sample reservoir 504" (7:13-26 and Fig. 5), but it must work together with the junction to perform this function, so the structures

disclosed at 7:51-9:15 are also required. In the '483 patent, the reservoir corresponds to "fluid reservoir 280" or "fluid reservoir 380," but it must change shape and interact with other components as disclosed at 12:15-15:16 or 17:51-20:4 to direct fluid flow.

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CERTIFICATION BY COUNSEL

I hereby certify that the **JOINT CLAIM CONSTRUCTION BRIEF** complies with the type and number limitations set forth in the July 21, 2019 Scheduling Order ¶ 16 (D.I. 24). The total number of words, including Plaintiff's and Defendants introductions and footnotes, but excluding the cover page, table of contents, table of authorities, and signature page, is 19,283, according to the word processing system used to compile the brief. The text of the brief is 14-point, Times New Roman.

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